SPRING 2000

TRIALS SEARCH GUIDE

HIV Clinical Trials in California

Compiled by the Community Consortium
UCSF Positive Health Program at San Francisco General Hospital

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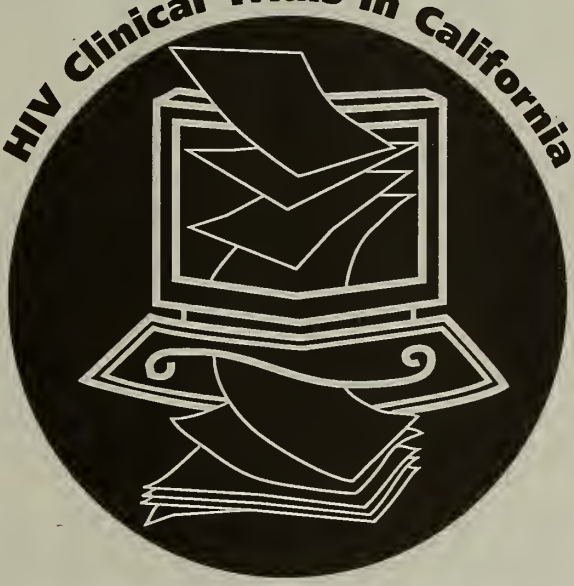
TRIALS SEARCH GUIDE

HIV Clinical Trials in California



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UCSF Positive Health Program at San Francisco General Hospital

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About the Community Consortium

The purpose of the Community Consortium is to improve the quality of primary medical care for people living with HIV/AIDS in the San Francisco Bay Area.

The Community Consortium is an association of licensed health care providers who care for the majority of people with HIV infection in the Bay Area. We work in private practices, neighborhood clinics, community hospitals, jails and correctional systems, academic medical centers and health maintenance organizations. Our administrative base is the UCSF Positive Health Program at San Francisco General Hospital Medical Center.

We achieve our purpose by ensuring that primary care providers in the Bay Area have the latest information on the most effective treatments for HIV disease, by evaluating a broad range of promising treatments and treatment strategies, and by influencing public policy that directly impacts the provision of primary medical care to people with HIV infection. We believe that all people with HIV infection should have access to the highest quality health care, and that this goal can only be achieved if there is cooperation among health care providers and people with HIV infection, and if existing resources are maximized through innovative and collaborative approaches to improving health care.

Our vision is that all people with HIV infection in our community will benefit from advances in HIV care, and that we will see the day when HIV is no longer a life-threatening disease.

Introduction

The *Trials Search Guide to HIV Clinical Trials in California* is a listing of all the clinical trials currently open in California that are related to HIV and AIDS. The *Guide* is primarily a resource for people infected with HIV, but is also used by HIV providers to educate their HIV-infected clients and patients.

A clinical trial is a study that tests experimental medicines in human beings. Any drug that is approved by the Food and Drug Administration (FDA) must undergo several clinical trials first. For people with HIV, clinical trials provide an opportunity to receive promising new medical treatments, usually for free.

Because the drugs tested are experimental, clinical trials involve some risks for patients. The *Guide* only includes studies that have been reviewed and approved by an Institutional Review Board, which is a committee set up to ensure that studies involving human subjects are ethical and scientifically sound. No endorsement is made of any trial described in the *Guide*, but every reasonable effort has been made to present information that is accurate, comprehensive and up-to-date. However, eligibility and other criteria are subject to change, trials may close to patient enrollment at any time, and new trials may begin without our knowledge.

Included in this *Guide* is a questionnaire form you can use to receive a personalized *Trials Search* listing of all the clinical trials for which you may be eligible to join within your area of California. This free service is based on confidential information about your medical history and current health status that you supply us on the questionnaire form. Call (800) 492-5777 if you would like to receive a second *Trials Search* questionnaire form, or if you have any questions about the service.

In addition, the Community Consortium welcomes information about all clinical trials available throughout the United States for inclusion in the national *Trials Search* database. Any trial that has been reviewed by an Institutional Review Board may be included. If you have information that may be appropriate for publication, please call the Consortium at (415) 476-5777 or (800) 492-5777.

Trials Search and the database HIV Clinical Trials in the United States are also available on the Internet at:

http://hivinsite.ucsf.edu/tsearch

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TRIALS SEARCH AND GUIDE EDITORIAL STAFF
Thomas Mitchell, Project Director
David Townley, Trials Search Coordinator and Guide Editor
Zach Weingart, Technical Coordinator

The editorial staff of the Guide is indebted to the following for invaluable assistance:

• Research staff at more than 60 trial sites who furnished the bulk of the information contained in the Guide. This project would not have been possible without their considerable expertise and generous contribution of time and energy.

The following publications for their reliability and usefulness:

• *AIDS/HIV Treatment Directory* published by the American Foundation for AIDS Research (AmFAR).
• *Bulletin of Experimental Treatments for AIDS (BETA),* from the San Francisco AIDS Foundation.
• *Treatment Issues* from the Gay Men's Health Crisis (GMHC) for the Glossary of Medical Terms which is a reference and basis for some of our glossary entries. The online Guide uses the GMHC Glossary as a whole.

An Association of Bay Area
HIV Health Care Providers

The Community Consortium is part of the
UCSF Positive Health Program at San Francisco General Hospital
Medical Center.

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How to use this Guide

The *Trials Search Guide* is written for people who are living with HIV disease and their health care providers. The *Guide* should be used in combination with other resources for learning about HIV disease. People interested in participating in clinical trials should discuss them with their physicians or health care providers. The *Guide* is most useful to people who already know something about their own health and about HIV. If you think you need to learn more, talk to your health care provider and contact some of the Resources beginning on page 121.

Understandable language

When learning about HIV and clinical trials, one of the stumbling blocks can be confusing medical jargon. We have tried to avoid using technical language whenever possible, but sometimes there is no simple way to describe technical information. If you come across a word or idea that you don't understand, you can check the Glossary on page 125. It may be helpful to discuss any remaining questions with your health care provider, or the contact person listed for the clinical trial. More information is also available from one or more of the Resources listed on page 121.

Other programs for treatment access

Receiving treatment for HIV and its related conditions can be complicated and confusing. If a medication you are seeking is not being studied in a clinical trial in your area, check page 89 for a listing of Expanded Access, Compassionate Use and Treatment IND Programs. If the treatment has been approved for sale, but you need help to pay for it, check the list of AIDS Drug Assistance Covered Drugs and pharmaceutical company sponsored Patient Assistance programs on pages 97-100.

Questions about clinical trials, and issues for special groups

The *Guide* also includes sections that answer common questions about clinical trials, describe how to join a clinical trial, and discuss issues about clinical trials for women, children, youth and people who use injection drugs. These sections are found on pages 101 through 113.

Trial Finder and Trial Descriptions

The 147 trials listed in the *Guide* are arranged by the disease or condition being studied, or by the group of people for whom the study is intended. Trial Finder on pages 3 - 8 is a quick reference for trials in which you may be interested.

If you are interested in a certain drug or treatment for a particular disease, you can also look it up in the Index, starting on page 133. The Index will tell you which page to turn to in the *Guide*.

How to use this Guide

For each clinical trial, we include the following information:

Title: This is the official name of the trial. Most trials also have letters or numbers given before the title. This is the protocol number. For example, ACTG 276 means this is AIDS Clinical Trials Group study number 276.

Type of Treatment: This lists the type or "class" of drugs being tested in the study. The different types of anti-HIV drugs attack the virus in different ways. Older anti-HIV drugs such as AZT (also called 2DV), ddI, ddC and d4T are all a type of drug called a "nucleoside analog". Some newer drugs are called "protease inhibitors" and "non-nucleoside reverse transcriptase inhibitors".

Purpose: This is what the researchers are trying to learn from the trial. Below are a few of the most common reasons why studies are done.

- To learn if a drug is safe for people to take.
- To learn if a drug works.
- To compare two or more drugs.
- To compare two or more doses of the same drug.

About the study: This section describes what will happen during a trial, from the patient's perspective. We tell you how long the trial lasts, if you will know what drugs you are taking, how the drug is given (for example, pill, liquid or injection), if there are an unusual number of required visits to the clinic, or if you need to stay in the hospital.

Required: These are the entry requirements that you must meet before you can join the study. These are sometimes called "inclusion criteria." We have space to list only a few of the most important entry requirements. In many cases, there will be others.

Not allowed: You cannot join the study if you fit any of these criteria. These are sometimes called "exclusion criteria." Again, only the most important exclusion criteria are included. You may not be able to join this particular study because there is a good chance that you would be harmed by the study drug. Researchers examine your medical history and your laboratory tests to make sure you are not at "high risk" for experiencing harmful side effects. Many clinical trials require that your laboratory tests be "within normal limits," or at least in a safe range. This is to make sure you don't already have a medical problem that might become worse if you take the drug.

Women who are pregnant or breastfeeding may also not be able to join a clinical trial. This is because it is not known if taking the drug will harm the baby. Usually, women who have sex with men, and men who have sex with women, must agree to use birth control while they are in the study.

Location: This is where you need to go to participate in the study (the study "site"). We also give you the name of the person to call if you are interested. In most cases, you don't have to be a patient at the hospital or clinic where the study is located in order to join the study. For some studies, your doctor must contact the site first.

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New

1. CSF Penetration and HAART: Indinavir, Abacavir, Nevirapine, Nelfinavir, ddI, Delavirdine

Title:

Role of CSF Penetration of Antiretroviral Drug Combination in Treatment-Related, Acute-Phase Viral Decay in CSF

Type of treatment:

Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Indinavir: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare the effects of two drug combinations, one with high ability to penetrate spinal fluid and one with low ability, on the reduction of HIV RNA viral load in the spinal fluid.

About the study:

Patients are assigned by chance to one of two treatment groups. The first group will take indinavir, abacavir and nevirapine (high CSF penetration). The second group will take nelfinavir, ddI and delavirdine (low CSF penetration). Patients will know which medications thay are taking and will take study medications for two weeks. During the two-week treatment phase, patients will have six spinal taps. A spinal tap is the removal of a small amount of spinal fluid (CSF) from the spinal canal by inserting a needle in the space between two vertebrae in the lower back. During the follow-up phase, patients will have three more spinal taps at Months 1, 3 and 12. Patients will also undergo neurological and neuropsychological tests at baseline and at Day 14. The study lasts one year. **Patients will be paid $100 for the first spinal tap and $125 for each additional spinal tap they undergo.**

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: both blood and CSF should be more than 7,000 copies/mL
- HIV positive
- Either antiretroviral naive or off prior therapy for at least five months prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Active alcohol and/or substance abuse which may interfere with the study
- Severe dementia or other neurological diseases

Location:

SFGH Department of Neurology
Annelie Nilsson
(415) 206-4328
-or-
Richard W. Price, MD
(415) 206-3208

New

2. HIV Infection and Sanctuary Sites: Indinavir, d4T, ddI

Title:

A Pharmacokinetic and Virologic Analysis of HIV Sanctuary Sites in Antiretroviral Naive Patients Receiving Didanosine, Stavudine, and Indinavir Therapy (HAART)

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how ddI, d4T and indinavir are processed by the body and to see what amount of these drugs appears in the semen, lungs, spinal fluid and tonsils of HIV-infected patients who have not taken antiretroviral medications before. To measure the HIV RNA viral load in these areas.

About the study:

At baseline, patients will undergo blood and urine tests, have a physical exam, give a semen specimen and have a bronchoscopy, lumbar puncture (spinal tap) and tonsil biopsy performed. A bronchoscopy is a procedure whereby a small flexible tube is inserted into the lungs through the mouth for examination and/or specimen collection. A lumbar puncture is the removal of a small amount of spinal fluid from the spinal canal by inserting a needle into a space between the bones of the lower back. A tonsil biopsy is the surgical removal of a small piece of tonsil tissue. After baseline testing, patients will start taking ddI, d4T and indinavir

for six months. Patients will have blood tests once a month, been seen by a physician at Months 1, 3 and 6, have additional bronchoscopies and spinal taps at Months 3 and 6, and have a final tonsil biopsy at Month 6. The study lasts seven months and **patients will be paid $4,000 for completing the study.**

Required:

- CD4 cell (T-cell) range: at least 350
- Viral load range: at least 2,000 copies/mL
- HIV positive males
- Between 21 and 55 years old

Not allowed:

- Prior use of any antiretroviral medications
- Females
- Use of aspirin or other nonsteroidal anti-inflammatory drugs within two weeks of study entry
- Past bleeding disorders
- Current symptoms of urinary tract infection
- Immunizations or acute illnesses within one month of study entry
- Patients who have had their tonsils removed

Location:

UCSF Infectious Diseases Research
Juliana Kipps, RN
(415) 476-5398

New

3. HIV Infection, Early Intensification: Abacavir

Title:

ACTG A5064: A Pilot Study of Early Treatment Intensification of Antiretroviral Therapy

Type of treatment:

Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if adding abacavir (Ziagen) to a three or more-drug combination is effective in lowering the amount of HIV In the blood of patients who have recently started potent antiretroviral treatment.

About the study:

Patients are assigned by chance to add abacavir or placebo to their current drug combination. Abacavir and its placebo are pills and taken twice a day. Neither patients nor their doctors will know which they are receiving. Only abacavir and placebo will be provided by the study; all other medications must be obtained by prescription or by other means. Study visits are once a month for the first three months, then every two months. The study lasts 36 weeks. All patients will participate for at least 12 weeks. Patients whose HIV viral load levels are too high at Week 12 will discontinue from the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: between 501 and 10,000 copies/mL **and** a 1 or more $\log_{10}$ decrease in HIV viral load between 49 and 70 days of beginning potent antiretroviral therapy
- HIV positive
- At least 13 years old
- Must be on stable (no changes) potent antiretroviral therapy which was started at least 28 days ago

Not allowed:

- Prior use of abacavir
- Women who are pregnant or breastfeeding
- Current use of immunomodulators (such as interleukins or interferons) or investigational drugs
- Any immunizations within 21 days prior to study entry
- Antiretroviral therapy for more than 90 days prior to study entry
- Any cancers requiring chemotherapy
- Any active infections requiring treatment within 21 days prior to study entry
- Unexplained fever of more than 38.5 C or 101.3 F for any seven consecutive days during the 30-day period prior to study entry

Location:

Stanford University Medical Center
Sylvia Stoudt, RN
(650) 498-4040

New

4. HIV Infection: AG-1549, Nelfinavir

Title:

AG1549-508: A Double-Blind, Randomized, Placebo-Controlled Study of AG-1549 in Combination With Viracept and Two Nucleoside Reverse Transcriptase Inhibitors in HIV-Infected Subjects Who Failed an Initial Non-Nucleoside Reverse Transcriptase Inhibitor-Containing Regimen

Type of treatment:

AG-1549: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see if AG-1549, an experimental NNRTI, when combined with Viracept (nelfinavir) and two new NRTIs can lower the amount of HIV in the blood of those patients who failed an initial treament containing an NNRTI (efavirenz, delavirdine or nevirapine).

About the study:

All patients will take nelfinavir plus two new NRTIs (such as AZT, ddI, ddC, 3TC, d4T or abacavir). In addition, patients are assigned by chance to take one of two doses of AG-1549 or to take a placebo. Neither patients nor their doctors will know to which group they have been assigned until the study is completed. Nelfinavir, AG-1549 and its placebo are pills and taken by mouth twice a day. Study visits are once a month and the study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 2,000 copies/mL
- HIV positive
- At least 18 years old
- Currently taking an NNRTI plus at leats one NRTI for at least 28 days and be failing that treatment as shown by an absence of a significant decrease in viral load

Not allowed:

- Prior use of AG-1549 or any protease inhibitors
- Women who are pregnant or breastfeeding
- Use of investigational drugs, chemotherapy or radiation therapy, or immunomodulators (interferons, interleukins) within 30 days of study entry

Location:

HIVCare,
Saint Francis Memorial Hospital
Mark Bowers
(415) 353-6215

Institute for HIV Research,
CPMC - Davies Campus
Steve Collinson, RN
(415) 600-6660

St. Luke Medical Group & Clinical Trials
Ida Proctor
(619) 235-0501

New

5. HIV Infection: Abacavir/3TC/AZT (Trizivir), Abacavir, Combivir

Title:

ESS 40005: A Phase IIIB Randomized, Multicenter Study of the Efficacy and Safety of Combivir 1 Tablet PO BID Plus Ziagen 300mg PO BID Versus an Abacavir 300mg/Lamivudine 150mg/Zidovudine 300mg Combination Tablet PO BID, Administered for 24 Weeks in Subjects With HIV-Infection

Type of treatment:

Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Abacavir/3TC/AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Combivir: antiretroviral, nucleoside analog

Purpose:

To compare the safety and effectiveness of a new triple combination tablet of abacavir/3TC/AZT (called trizivir) to abacavir plus combivir.

About the study:

Patients are assigned by chance to receive the new triple combination tablet of abacavir/3TC/AZT or to take Combivir plus abacavir. Patients will know which form of these three medications they are taking. The abacavir/3TC/AZT tablet is taken by mouth twice day while abacavir and Combivir are two tablets taken by mouth twice a day. Study visits are every two months and the study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: more than 200
- Viral load range: 400 copies/mL or less
- HIV positive
- Al least 18 years old
- Must be taking Combivir plus abacavir with or without a protease inhibitor or an NNRTI for at least 16 weeks prior to study entry
- The Combivir/abacavir-containing treatment must be the first antiretroviral treatment patients have ever taken

Not allowed:

- Women who are pregnant or breastfeeding
- Active alcohol and/or substance abuse which may interfere with the study
- Patients with symptoms of acute hepatitis or are currently being treated for chronic active hepatitis
- Enrollment in another investigational drug study
- Cancers requiring chemotherapy within four weeks prior to study entry or the need for such throughout the study
- Use of immunomodulators, such as interferons, corticosteroids, interferons or vaccines within four weeks prior to study entry

Location:

St. Luke Medical Group & Clinical Trials
Ida Proctor
(619) 235-0501

New

6. HIV Infection: BMS-232632, 3TC, d4T, Nelfinavir

Title:

A1424-008-002: Evaluation of the Safety and Antiviral Efficacy of a Novel HIV-Protease Inhibitor, BMS-232632, in Combination With d4T and 3TC as Compared to a Reference Regimen

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
BMS-232632: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare two different doses of the new protease inhibitor, BMS-232632, with nelfinavir when combined with d4T and 3TC for safety, tolerability and effectiveness in lowering the amount of HIV in the blood.

About the study:

All patients will take 3TC and d4T and are assigned by chance to one of two doses of BMS-232632 or nelfinavir. Patients will know if they are taking BMS-232632 or nelfinavir but will not know which dose of BMS-232632 they are taking until the study ends. All study medications are pills and taken by mouth. Study visits are once a month for the first six months, then every other month. The study lasts 48 weeks

Required:

- CD4 cell (T-cell) range: more than 100 **or** more than 75 if no past AIDS-defining illnesses
- Viral load range: more than 2,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- Prior use of any antiretroviral medications
- Past pancreatitis
- Hepatitis within 30 days of study entry
- Active opportunistic infections at enrollment
- Numbness or tingling in the hands, feet or face that would indicate a nerve problem
- Women who are pregnant or breastfeeding

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

Slauson Plaza Medical Group
Elvia Pena
(323) 869-5391

New

7. HIV Infection: Brand of S6F1 Antibody

Title:

Brand of S6F1 Antibody Pharmacokinetic and Dose-Ranging Study in HIV Seropositive Patients

Type of treatment:

Brand of S6F1 Antibody:

Purpose:

To see if Brand of S6F1 Antibody is safe and well-tolerated and if it has any effect on the amount of HIV in the blood or on T-cell counts. To see how Brand of S6F1 Antibody is processed by the body.

About the study:

This is a dose escalation study. This means that the first group of patients to enter the study will receive the lowest dose of Brand of S6F1 Antibody. If no bad side effects are seen, the next group of patients will receive a higher dose of Brand of S6F1 Antibody, and so forth until the highest dose researchers plan to study has been given or the highest dose that does not cause serious side effects has been found. Brand of S6F1 Antibody is given once on day 1 by infusion into a vein. The infusion will take about 15 minutes and patients will be monitored in the clinic for 90 minutes following the infusion. Study visits are every day for the first week, then on days 14, 21, 28, 30 56 and 58. The study lasts eight weeks.

Required:

- CD4 cell (T-cell) range: between 200 and 500
- Viral load range: at least 50,000 copies
- HIV positive
- At least 18 years old
- Patients must be naive to antiretroviral medications **or** have not taken any antiretroviral medications for the past two months **or** have been on stable antiretroviral medication for the past two months and agree to continue it throughout the study

Not allowed:

- Any previous use of Brand of S6F1 Antibody
- Women who are pregnant or breastfeeding
- Any chemotherapy within 8 weeks prior to study entry or the need for such during the study
- Any current acute illness
- Current substance abuse or other behavioral problems
- Use of any experimental medications within 60 days of study entry

Location:

Eisenhower Medical Center
Donald W. Northfelt, MD, F.A.C.P.
(760) 776-1633

New

8. HIV Infection: GW 4339908, Amprenavir, Abacavir, 3TC

Title:

APV 20001: A Randomized Multi-Center, Partially Double-Blinded, Repeat-Dose, Cross-Over Study to Assess the Safety, Tolerability, Pharmacokinetics, and Antiviral Effect of Two Doses of GW 433908 Compared With Amprenavir (1200 mg BID) When Given for 28 Days to Subjects Infected With HIV-1

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Amprenavir: antiretroviral, protease inhibitor
GW 433908: antiretroviral, protease inhibitor

Purpose:

To see if GW 433908 (amprenavir prodrug) is safe, well-tolerated and effective in lowering the amount of HIV In the blood when combined with abacavir and 3TC. To see how these drugs are processed by the body.

About the study:

There are three treatment periods in this study. All patients will take abacavir and 3TC. During **Treatment Period 1**, patients are assigned by chance to receive one of two doses of GW 433908 or to take amprenavir capsules to take with abacavir and 3TC.. After 28 days (**Treatment Period 2**), patients who were taking amprenavir capsules will switch to one of two doses of GW 433908 and those who were taking GW 433908 will switch to amprenavir capsules. Patients will take this combination until Day 42. Study visits are at Days 1, 7, 14, 21, 28, and 42. On Days 1, 28 and 42, patients will have multiple blood tests done throughout the day. Upon completion of Day 42, patients will have the option to continue the study taking amprenavir, abacavir and 3TC for an additional 18 weeks. Patients continuing on with this 18-week phase (**Treatment Period 3**) will have study visits at Weeks 8, 12, 16 and 24. The study lasts either six weeks or 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 5,000 copies/mL
- HIV positive
- Between 18 and 65 years old

Not allowed:

- Prior use of any protease inhibitors
- More than four weeks use of any NRTIs or NNRTIs. Nevirapine or efavirenz use must be stopped at least 14 days prior to study entry
- Serious medical conditions, such as diabetes, congestive heart failure, etc.
- Hepatitis or pancreatitis within the past six months
- Clinical diagnosis of AIDS
- Use of radiation, chemotherapy or immunomodulators (interleukins, interferons) within 30 days of study entry
- Women who are pregnant or breastfeeding

Location:

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

New

9. HIV Infection: Indinavir, Ritonavir

Title:

ACTG A5055: A Phase I/II, Randomized, Open-Label Study of the Safety and Pharmacokinetics of Indinavir + Ritonavir Therapy in HIV-Infected Subjects Failing Amprenavir, Nelfinavir, Saquinavir, or Nelfinavir/Saquinavir Combination Therapy

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To see how the body processes indinavir and ritonavir when taken in two different doses with two other NRTIs, such as AZT, ddI, ddC, 3TC, d4T or abacavir. To see if these combinations have any effect on lowering the amount of HIV in the blood stream.

About the study:

During the screening, all patients will have a genotype test done to see if indinavir or ritonavir might fail to reduce the HIV viral load. Patients may be excluded from participating in this study based upon the result of this test. Eligible patients will be assigned by chance to receive one of two dose schedules of indinavir and ritonavir to take with two NRTIs, one of which will be new for the patient. Patients will know which doses they are taking. Study visits at Weeks 1, 2, 4, then every four weeks. At Week 2, patients will have a 12-hour study visit at the clinic for multiple blood tests. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: between 500 and 100,000 copies/mL
- HIV positive
- At least 18 years old
- Must have been treated with amprenavir, nelfinavir, saquinavir or nelfinavir/saquinavir combination therapy plus 2 NRTIs for at least 12 weeks prior to study entry
- Must have no experience with at least one NRTI

Not allowed:

- Active opportunistic infections within 14 days of study entry
- Prior use of indinavir or ritonavir
- Use of any NNRTIs within 30 days of study entry
- Women who are pregnant or breastfeeding
- Active immunizations within 21 days of study entry
- Any cancers requiring chemotherapy
- Use of any immunomodulators (such as interferons or interleukins) or investigational drugs within 30 days of study entry
- Unexplained fever of more than 38.5 C or 101.3 F for any 7 consecutive days during the 30-day period prior to study entry

Location:

Marin County Specialty Clinic
Joann Volinski, RN
(415) 499-7377

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

New

10. HIV Infection: Nelfinavir, Efavirenz, Combivir, d4T, ddI

Title:

AG 1343-1127: A Randomized, Open-Label Study of Nelfinavir or Efavirenz in HIV-1 Infected, Antiretroviral Naive Patients

Type of treatment:

Combivir: antiretroviral, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare nelfinavir (Viracept) to efavirenz (Sustiva) when combined with Combivir for the effectiveness in lowering the amount of HIV in the blood in HIV positive patients who have never taken antiretroviral medications before.

About the study:

All patients will take Combivir (AZT/3TC combination tablet) and are assigned by chance to take nelfinavir or efavirenz in addition. If patients do not respond to their assigned therapy or if they experience bad side effects, they will be switched to an alternative treatment plan. Patients originally assigned to take nelfinavir plus Combivir will be switched to efavirenz plus d4T plus ddI. Patients who initially received efavirenz plus Combivir would be switched to nelfinavir plus d4T plus ddI. Patients will always know which medications they are taking. The study lasts from 48 - 72 weeks with 11 - 15 study visits during that time.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- More than one weeks use of any antiretroviral medications
- Women who are pregnant or breastfeeding

Location:

St. Luke Medical Group & Clinical Trials
Rebecca Gonzalez
(619) 235-0501

UC Irvine Medical Center
Angie Pezina, RN
(714) 456-7612

New

11. HIV Infection: Observational, Longitudinal

Title:

ACTG A5001: Adult AIDS Clinical Trials Group Longitudinal Linked Randomized Trials (ALLRT) Protocol

Type of treatment:

Observational: none

Purpose:

To see how the body responds to HIV infection and its treatment over several years.

About the study:

Patients enrolling in this study must currently be in an ACTG treatment study or have been in one within the last eight weeks (called the parent study). The parent study must provide (or have provided) anti-HIV therapy that is assigned by chance. At study entry, a

medical history, medication history, and laboratory tests results will be taken from the parent study records. A routine physical examination will be done including body measurements such as thigh, hip, waist, arm and neck to learn about changes in body shape. Neurological exams will also be given to test the way patients think through or understand information. Some of these tests are paper and pencil tests. Patients will need to return to the clinic for study visits every 16 weeks (about three times a year). These visits will be at the same time as the parent visit, if possible. The study will last about five years.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Current participation in an approved parent ACTG study **or** completed an approved parent ACTG study within the past eight weeks

Not allowed:

- Active alcohol and/or substance abuse which could interfere with the study

Location:

Marin County Specialty Clinic
Joann Volinski, RN
(415) 499-7377

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

New

12. HIV Infection: Pegylated Interferon

Title:

P00737: Antiretroviral Activity and Tolerability of PEG-Intron in HIV-Infected Subjects Failing HAART

Type of treatment:

Interferon, Pegylated: immune modulator

Purpose:

To see if pegylated interferon (a long-acting form of interferon) can lower the level of HIV in the blood of patients who have failed Highly Active Antiretroviral Therapy (HAART). To see if pegylated interferon (PEG Intron) is well-tolerated.

About the study:

Patients will have genotype testing done at screening to see if there are any HAART drugs that will not work for a patient's particular virus. Patients are assigned by chance to receive one of four doses of PEG Intron or to receive a placebo. PEG Intron and its placebo are given by injection under the skin once a week. At Week 4, patients will change their HAART therapy based on the results of the genotype test done during screening. Study visits are once a week for the first month, then once a month. Patients will have another genotype test done at Week 28 to see what, if any, changes have occurred after new HAART therapy and PEG Intron therapy have been given. The study lasts 32 weeks.

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: at least 2,0000 copies/mL
- HIV positive
- At least 18 years old
- Taking HAART medications for at least six months, and on the current HAART treatment for at least six weeks prior to study entry
- Viral load increase of threefold or more from the previous low point in the last six months **or** from a previous lowest level of less than 500 copies/mL on the current HAART therapy

Not allowed:

- Active opportunistic infections
- Any interferon therapy within the last six months
- Use of any investigational drug within one month of study entry
- Women who are pregnant or breastfeeding
- Use of anti-seizure medications
- Unwilling to wait four weeks until the HIV resistance profile is available before changing current HAART

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

New

13. HIV Infection: Remune

Title:

ACTG A5057: A Phase III, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Effect of Immunization With an HIV Immunogen on the Time to Virologic Relapse in Individuals Receiving Potent, Suppressive Antiretroviral Therapies

Type of treatment:

Remune: immune modulator

Purpose:

To see whether Remune together with antiretroviral medications can keep the level of HIV virus in the blood low for a longer period of time than with antiretroviral medications alone.

About the study:

Patients are assigned by chance to add Remune or Remune placebo to their current antiretroviral medications. Remune and its placebo are given by injection into a muscle at the beginning of the study and every 12 weeks thereafter. Neither patients nor their doctors will know which they are receiving until the study ends. Antiretroviral medications are not provided by the study and should be obtained by prescription or by other means. If patients experience an HIV virologic relapse (viral load > 2,000 copies/mL) they will be encouraged to switch to a new drug combination. Study visits are every 12 weeks and patients will be in this study until the last patient to enroll has completed 96 weeks of treatment.

Required:

- CD4 cell (T-cell) range: at least 300
- Viral load range: less than 500 copies/mL for at least 12 weeks prior to study entry
- HIV positive
- At least 18 years old
- Must be on a stable (no changes) antiretroviral treatment for at least 12 weeks prior to study entry and agree to remain on that treatment unless they experience drug-related side effects or experience treatment failure

Not allowed:

- Women who are pregnant or breastfeeding
- Any infections or other acute illnesses within 30 days prior to study entry
- Any cancers requiring chemotherapy
- Past radiation treatment of the lymph nodes
- Prior use of any HIV vaccine
- Use of GM-CSF, G-CSF, M-CSF, interferons, interleukins, hydroxyurea or any immunizations within 30 days of study entry

Location:

Marin County Specialty Clinic
Joann Volinski, RN
(415) 499-7377

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

New

14. HIV Infection: T-20

Title:

T20-208: Tolerance and Pharmacokinetics (PK) of Carbonate and Tris Buffer High Strength (100 mg/mL) Formulations of T20/Ro 29-9800 (HIV-1 Fusion Inhibitor) Compared to the Current Carbonate Formulation (50 mg/mL), Each at Doses of 75 and 100 mg BID, in HIV Infected Patients

Type of treatment:

T-20: antiretroviral, fusion inhibitor

Purpose:

T-20, an experimental new class of anti HIV drug, has currently been studied using a specific formulation (carbonate). This study will test different doses of the carbonate formulation plus a new formulation (called tris) of T-20, to see if they are well-tolerated and to see how they are processed by the body. To see if T-20 can be given with fewer injections and still be effective in lowering the amount of HIV in the blood.

About the study:

Patients are assigned by chance to one of four dose groups of T-20 to take with their backround therapy (NRTIs, NNRTIs or protease inhibitors). Patients will switch doses of T-20 after 14 days and switch back to the original dose after 28 days. The dose differences will dictate how many injections per day that patients must receive. On Days 14 and 28, patients will have all-day study visits for multiple blood tests. Study visits are once a month and the study lasts for 48 weeks or possibly longer.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 400 copies/mL
- At least 18 years old
- HIV positive
- Patients and/or caregivers must be willing to give injections

Not allowed:

- More than seven days use of T-20
- Women who are pregnant or breastfeeding
- Active alcohol and/or substance abuse which could interfere with the study
- Use of other experimental medications

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

New

15. HIV Infection: Thymus Radiation

Title:

H6325-15521-01A: Lymphoid Irradiation With Thymic Shielding in Subjects With HIV Disease Who Are Failing Highly Active Antiretroviral Therapy

Type of treatment:

Radiation:

Purpose:

To see if low-dose radiation (while protecting the thymus) can help to reduce the total number of lymph cells infected with HIV, and to improve the immune function in people with advanced HIV disease who have failed multiple combinations of antiretroviral drugs.

About the study:

All patients will receive a CT scan of the thymus area as part of the screening process to determine the absence or presence of the patient's thymus. Patients will be divided into two groups; those with present thymus and those with absent thymus. Patients in both groups will either take antiretroviral therapy or antiretroviral therapy plus low-dose radiation of the lymph nodes. Patients who choose to undergo radiation will do so in a dose-escalating manner. This means that the first group of patients to enroll will receive the lowest dose of radiation. If no bad side effects are seen, the second group of patients will receive a higher dose, and the third group will receive the highest dose. Radiation therapy will be performed at Moffitt/Long Hospital and patients will be admitted to the General Research Clinical Center at San Francisco General Hospital for 24 hours after each radiation dose. Those patients choosing antiretroviral therapy alone will receive another CT scan of the thymus at Week 20. Those receiving radiation will receive CT scans at Weeks 3, 16, 52 and 76. Patients receiving radiation will also be asked and encouraged (but not required) to have biopsies (3) done over the course of the study. A biopsy is the surgical removal of a small piece of a lymph node. Patients receiving radiation will also have multiple blood tests performed throughout the study. Patients taking antiretroviral therapy alone will be in the study for at least six months and those taking antiretroviral therapy with radiation will be in the study for at least one year.

Required:

- CD4 cell (T-cell) range: less than 75
- Viral load range: more than 5,000 copies/mL after at least 16 weeks of continuous therapy
- HIV positive
- Age: at least 18 years old
- Must have failed at least two HAART treatments containing different protease inhibitors and one treatment containing an NNRTI and/or patients who have no treatment options remaining in the opinion of the study investigator and the patient's doctor

Not allowed:

- Past cancers except KS of the skin
- Use of immunomodulators, chemotherapy or radiation therapy
- Active alcohol and/or substance abuse which may interfere with the study
- Women who are pregnant or breastfeeding
- Past opportunistic infections which may be reactivated
- Significant medical conditions including lung, heart, kidney, liver or neurological diseases

Location:

Gladstone Institute of Virology and Immunology
Diane Schmidt
(415) 695-3820

New

16. HIV Infection, Early: Combivir, Abacavir, Amprenavir

Title:

ACTG 371: A Trial to Evaluate the Safety and Efficacy of Quadruple Drug Induction Treatment with Lamivudine/Zidovudine (3TC/ZDV) Plus ABC (Abacavir, 1592U89) Plus APV (Amprenavir, 141W94) Followed by Partially Blinded Maintenance Treatment in Subjects with Acute HIV Infection or Recent Seroconversion

Type of treatment:

Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Amprenavir: antiretroviral, protease inhibitor
Combivir: antiretroviral, nucleoside analog

Purpose:

To see if taking a four-drug combination of anti-HIV medications during the early stage of HIV infection can make the virus in the blood and body tissues undetectable and whether the virus will stay undetectable after these drugs are discontinued.

About the study:

All patients will take Combivir (AZT/3TC), abacavir and amprenavir twice a day for one year (Induction Phase). Study visits are once a month and include blood tests and limited physical exams. If the blood test at Week 48 indicates that the HIV viral load is below 200 copies/mL and if patients are still taking abacavir, they will begin a different part of the study (Maintenance Phase). At Week 52, continuing patients are assigned by chance to one of three groups. **Group A** will take Combivir plus abacavir plus amprenavir.

Group B will take Combivir plus abacavir placebo plus amprenavir. **Group C** will take Combivir placebo plus abacavir plus amprenavir. Study drugs are taken twice a day and patients will know they are taking amprenavir but will not know whether the other pills are drug or placebo until the study ends. Patients will take these study drugs for an additional 30 to 60 weeks, depending on whether they withdraw treatment or continue on the Maintenance Phase until Week 112. Study visits are once a month for this portion of the study. At Week 88, patients who have a viral load of less than 50 copies/mL and have no sign of virus in their blood cells will discontinue study medications and be followed through Week 112. Those patients who have a viral load of less than 50 copies/mL but have some virus in their blood cells will remain on maintenance therapy as will those patients with a viral load between 50 and 199 copies/mL. Patients with viral loads of 200 or more will be followed through Week 112 and will be given one of four options regarding their medications. The study lasts a little over two years.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 2,000 copies/mL within seven days of study entry **and** one of the following:
  - a negative ELISA within seven days of study entry **or**
  - a positive ELISA but negative or indeterminate Western Blot within 7 days of study entry **or**
  -a positive ELISA and Western Blot within seven days of study entry but with a documented negative ELISA or viral load less than 2,000 copies/mL within 30 days prior to study entry
- At least 16 years old

Not allowed:

- Prior use of any antiretroviral treatment
- Acute or chronic pancreatitis within 120 days prior to study entry
- Documented or suspected hepatitis within 30 days prior to study entry
- Use of HIV vaccines or any investigational drugs within 30 days prior to study entry
- Women who are pregnant or breastfeeding

Location:

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

17. HIV Infection: 3TC, AZT, Sustiva

Title:

EPV20001: A Phase II/III 48-Week, Randomized, Double-Blind, Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Lamivudine 300mg Once Daily vs Lamivudine 150mg BID in Combination With Zidovudine 300mg BID and Efavirenz 600mg Once Daily in Antiretroviral-Naive Adults With HIV-1 Infection

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)

Purpose:

To evaluate the safety of 3TC given once a day versus 3TC given twice a day when combined with AZT and Sustiva (efavirenz).

About the study:

All patients will take AZT twice a day and Sustiva once a day. In addition, patients are assigned by chance to take 3TC once a day or to take 3TC twice a day. Since patients will not know if they are taking 3TC once or twice a day, those patients assigned to take 3TC once day will also take a 3TC placebo. All medications are taken by mouth and will be provided by the study. Study visits are every two weeks for the first month, then once a month. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: more than 100
- Viral load range: more than 400 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- More than seven days use of any antiretroviral medications
- Women who are pregnant or breastfeeding

Location:

Harbor-UCLA Medical Center
Judith Christian, RN
(310) 222-5291

Institute for HIV Research,
CPMC - Davies Campus
Steve Collinson, RN
(415) 600-6660

Kaiser Permanente Clinical Trials Unit,
San Francisco
Anna Dowling, RN
(415) 202-3487

18. HIV Infection: ABT-378 / Ritonavir, Nevirapine

Title:

M98-888: A Randomized, Open-Label, Phase III Study of ABT-378/Ritonavir in Combination with Nevirapine and Two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) vs. Investigator-Selected Protease Inhibitor(s) in Combination with Nevirapine and Two NRTIs in Antiretroviral-Experienced HIV-Infected Patients

Type of treatment:

ABT-378/Ritonavir: antiretroviral, protease inhibitor
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To compare the safety and effectiveness of ABT-378/ritonavir (lopinavir) plus nevirapine plus two NRTIs with one or two other protease inhibitors plus nevirapine plus two NRTIs.

About the study:

All patients will take nevirapine plus two NRTIs, such as AZT, ddI, ddC, 3TC or d4T. In addition, patients are assigned by chance to take ABT-378/ritonavir or to take one or two protease inhibitors to be selected by the study investigator. Patients will know which medications they are taking. Study visits are once a month. Patients will take study medications for at least 48 weeks, at which time the study may be continued, based on safety and effectiveness data, until ABT-378/ritonavir is available for marketing in the United States.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: between 1,000 and 500,000 copies/mL
- HIV positive
- At least 12 years old
- Stable (no changes) antiretroviral therapy consisting of two NRTIs and one protease inhibitor for at least 12 weeks prior to study entry (patients may have had up to six weeks of a second protease inhibitor)
- At least one NRTI, other than ddC or abacavir, with which patients have no experience

Not allowed:

- Any active opportunistic infections requiring treatment within 30 days of study entry
- Women who are pregnant or breastfeeding
- More than seven days use of any NNRTIs, such as delavirdine, nevirapine or efavirenz
- Current use of systemic chemotherapy
- Use of any investigational drugs within 30 days of study entry

Location:

Center for Special Immunology
Sandra Casserella, RN
(714) 751-5800

Pacific Oaks Research Group
Kai Gu, RN
(310) 360-8800

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, ext. 3763

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

New

19. HIV Infection: AG-1549, Nelfinavir, Combivir

Title:

AG1549-504: A Randomized, Double-Blind, Placebo-Controlled Study of AG-1549 in Combination With Viracept (nelfinavir mesylate) and Combivir (zidovudine & lamivudine) in Treatment-Naive HIV-Infected Patients

Type of treatment:

AG-1549: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Combivir: antiretroviral, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To compare the safety, tolerability and effectiveness of AG-1549, a new NNRTI, when combined with nelfinavir (Viracept) and Combivir (AZT/3TC fixed dose) in treatment-naive HIV-infected patients.

About the study:

All patients will take nelfinavir and Combivir. Patients are assigned by chance to receive AG-1549 or placebo. Neither patients nor their doctors will know which they are receiving until the study ends. All study medications are pills and taken by mouth. Study visits are at Day 4, Day 8, Week 2, Week 3, Week 4, then once a month. This study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: more than 50
- Viral load range: more than 5,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- Prior use of any antiretroviral medications
- Women who are pregnant or breastfeeding

Location:

Harbor-UCLA Medical Center
Sally Kruger
(310) 222-3848

Institute for HIV Research,
CPMC - Davies Campus
Steve Collinson, RN
(415) 600-6660

New

20. HIV Infection: Abacavir (Ziagen)

Title:

COL30305: A Phase IV, Randomized, Open-Label, Multicenter, Twenty Four-Week Pilot Study to Evaluate the Efficacy and Safety of Continued Therapy With Two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) Plus One Protease Inhibitor (PI) Versus Switch to Two NRTIs Plus Ziagen (Abacavir) 300mg BID in HIV-1-Infected Adults With HIV-1 RNA <50 Copies/mL

Type of treatment:

Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if replacing a protease inhibitor with acabavir (Ziagen) is effective in keeping the HIV viral load below the level of detection in patients currently taking antiretroviral therapy which includes two NRTIs and a protease inhibitor.

About the study:

Patients are assigned by chance to continue their current initial antiretroviral therapy consisting of two NRTIs plus a protease inhibitor **or** to add abacavir to their current antiretroviral therapy. Those patients assigned to add abacavir will do so for four weeks, then will stop taking their protease inhibitor. Patients will take study medications for 24 weeks. Study visits are every two weeks for the first month, then once a month. This study lasts for 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: less than 50 copies/mL using Roche Ultrasensitive assay. Past viral load of <400 (Roche) or <500 (Chiron) for at least three months prior to screening
- HIV positive
- At least 18 years old
- Currently on initial combination antiretroviral therapy, consisting of two NRTIs plus one protease inhibitor, for at least six months prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of any NNRTIs or abacavir
- Acute hepatitis or chronic active hepatitis
- Use of radiation or chemotherapy within four weeks of study entry or the need for such throughout the study
- Any AIDS-defining illness within the past 30 days
- Active alcohol and/or substance abuse which may interfere with the study
- Treatment for an infection or other medical illness within 14 days of study entry

Location:

Kaiser Permanente Clinical Trials Unit, San Francisco
Anna Dowling, RN
(415) 202-3487

Pacific Horizon Medical Group
Jennifer Armfield
(415) 292-5481

21. HIV Infection: Abacavir, Efavirenz, ddI, Hydroxyurea

Title:

NZTA4008: A Phase IV 48-Week, Randomized, Open-Label,Multicenter Trial of Abacavir (300mg BID)/Efavirenz (600mg QD)/Didanosine (400mg QD) With or Without Hydroxyurea (500 mg BID) in HIV-1 Infected Subjects Failing Initial Therapy with Protease Inhibitor/3TC/ZDV (or d4T)

Type of treatment:

Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Hydroxyurea: cellular inhibitor
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if the combination of abacavir, efavirenz (Sustiva), ddI with or without hydroxyurea is safe, well-tolerated and effective in lowering the amount of HIV in the blood of patients who have failed their first drug combination which included a protease inhibitor, 3TC and either AZT or d4T.

About the study:

All patients will take abacavir, efavirenz and ddI. Patients are assigned by chance to receive hydroxyurea. Those patients who are assigned to take hydroxyurea will be further assigned by chance to begin taking hydroxyurea at the beginning of the study or to wait until Week 8 to start taking hydroxyurea. Patients will know which medications they are taking. Study visits are once a month for the first two months, then every two months. This study lasts about one year.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range:between 400 and 50,000 copies/mL
- HIV positive
- At least 13 years old
- Must have failed (did not achieve a viral load of less than 400 copies/ml within 16 weeks or maintain a viral load of less than 400 copies/mL after 16 weeks) their initial drug combination which included a protease inhibitor, 3TC and AZT or d4T

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of abacavir, ddI or any NNRTI (delavirdine, nevirapine, efavirenz)

Location:

East Bay AIDS Center
Lucinda Hopewell, PA-C
(510) 204-4109

Pacific Horizon Medical Group
Amy Sullivan
(415) 292-5477 ext. 480

St. Luke Medical Group & Clinical Trials
Rebecca Gonzalez
(619) 235-0501

22. HIV Infection: BMS-232632, Nelfinavir, ddI, d4T

Title:

A1424-007: Evaluation of the Safety and Antiviral Efficacy of a Novel HIV-1 Protease Inhibitor, BMS-232632, Alone and in Combination with d4T and ddI as Compared to a Reference Regimen

Type of treatment:

BMS-232632: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare the new protease inhibitor, BMS-232632, with nelfinavir when combined with ddI and d4T for safety, tolerability and effectiveness in lowering the amount of HIV in the blood of antiretroviral naive patients.

About the study:

Patients are assigned by chance to receive one of three doses of BMS-232632 or to receive nelfinavir to take in addition to d4T and ddI. Patients assigned to take BMS-232632 will not know which dose they are receiving until the study ends. All medications are pills and taken by mouth. Study visits are every two weeks for the first month, then once a month until Week 16, then once every two months. The study lasts 48 weeks. Some locations may provide payment for participation.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: between 2,000 and 200,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- Prior use of any antiretroviral therapy except for up to seven days use of NRTI therapy (AZT, ddI, ddC, d4T, 3TC)
- Use of any such NRTI therapy within 30 days of study entry
- Past or current pancreatitis or hemophilia
- Active opportunistic infections
- Women who are pregnant or breastfeeding

Location:

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

23. HIV Infection: CSF Viral Load

Title:

Cerebrospinal Fluid Analysis of HIV-1 Viral Burden in HIV-1-Infected Subjects: Response to Antiretroviral Therapy

Type of treatment:

Observational: none

Purpose:

To see what effect antiretroviral therapy has on the amount of HIV in the spinal fluid and to see what effect it has on neurological function.

About the study:

Patients in this study will have two lumbar punctures (spinal taps) at the beginning of the study and three more spinal taps during the course of one year. Spinal taps consist of a needle being passed into the spinal column between vertebra and having some fluid removed. **Patients are paid $75 for the first spinal tap, $100 for the second, and $125 for the next three**. Blood tests and neurological exams will also be performed at weeks 16 and 52. The study lasts one year.

HIV-negative volunteers will also be enrolled in this study. They will receive up to three lumbar punctures and **will be paid $125** for each LP (spinal tap).

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive or negative
- At least 18 years old
- Patients must be starting, changing or stopping antiretroviral therapy at the time of study entry

Not allowed:

- Brain mass lesions
- Neurological disorders such as cryptococcal meningitis, toxoplasmosis, severe psychiatric disorder or active drug or alcohol abuse
- Noncompliance with antiretroviral medications

Location:

SFGH Department of Neurology
Annelie Nilsson
(415) 206-4328
-or-
Richard W. Price, MD
(415) 206-3208

24. HIV Infection: DAPD

Title:

DAPD-101: An Open-Label, Dose-Escalation Study to Evaluate Safety, Tolerance, Pharmacokinetics, and Antiviral Activity of Oral DAPD in Patients Infected with HIV

Type of treatment:

DAPD: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if DAPD is safe, well-tolerated and if it has any activity against the HIV virus. To see how DAPD is processed by the body.

About the study:

This is a dose-escalating or dose-ranging study. This means that the first patients to enroll in the study will receive the lowest dose of DAPD. If no bad side effects are seen, the next group of patients will receive a higher dose and so forth until the highest dose researchers plan to study has been given. DAPD is a pill and taken by mouth twice a day and patients will be treated for 15 days. The twice-a-day dose that produces a satisfactory response in lowering the amount of HIV in the blood may be tested as a total daily dose (once a day). On Days 1 and 15, patients are required to spend all day in the research center for multiple blood tests. Patients will be followed for seven days after completion of study medication. The study lasts 22 days. **Patients will be paid $125 for each all-day visit on Days 1 and 15 for a total of $250.**

Required:

- CD4 cell (T-cell) range: at least 200
- Viral load range: between 5,000 and 100,000 copies/mL
- HIV positive
- Between 18 and 65 years old
- Patients who have taken antiretroviral medications in the past must have taken a combination containing AZT/3TC or d4T/3TC for more than six months and had a viral load of at least 5,000 copies/mL while on that treatment
- Patients on antiretroviral treatment must have received the same treatment for at least one month prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of ddI or ddC for longer than three months
- Use of investigational medications, immunomodulators (interleukins or interferons), prophylaxis for OIs (Septra, Bactrim is allowed) or corticosteroids
- Active opportunistic infections requiring treatment
- Malabsorption or severe diarrhea, defined as four or more watery stools per day for two weeks prior to study entry
- Any cancers requiring chemotherapy or radiation therapy
- Unexplained fever of 38.5 C (101.5 F) or more persisting for 14 days or more within a 30-day period prior to study entry
- Active alcohol and/or substance abuse which may interfere with the study

Location:

UCSF Positive Health Practice
at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296 ext. 312

25. HIV Infection: Delavirdine, AZT, Indinavir

Title:

M/3331/0072: An Open-Label,Parallel Group, Pilot Study of Safety, Tolerance, Pharmacokinetics and Pharmacodynamics of BID and TID Regimens of Delavirdine, Zidovudine, and Indinavir Sulfate in HIV-1 Infected Individuals

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Indinavir: antiretroviral, protease inhibitor

Purpose:

To compare the safety and effectiveness of twice-a-day doses versus three times a day doses of delavirdine, AZT and indinavir. To see how these two different doses are processed by the body.

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Each study listing includes:

- Name of study
- Purpose of study
- What the study involves
- Who can join the study
- Whether the study pays participants
- Names and phone numbers of people to call if you want to join the study or ask questions.

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It is important to answer each of the questions completely. If you have problems filling out the questionnaire, call our toll-free number for assistance. Your doctor or other health care provider can also help. A nurse or medical office staff person may be able to answer these questions on the telephone.

Trials Search *is a service provided by the Community Consortium, an association of Bay Area HIV health care providers. The Community Consortium is a part of the UCSF Positive Health Program at San Francisco General Hospital.*

Contact Information:

All information is mailed to you in a plain envelope. In some cases we may need to call you to clarify information on your questionnaire. Your name and other personal information is held in the strictest confidence.

NAME _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

TELEPHONE _____ FAX (for response by Fax) _____

May we leave a message? ❒ yes ❒ no Is this a private Fax? ❒ yes ❒ no

May we contact you by mail in the future? ❒ yes ❒ no

How did you hear about **Trials Search**? ❒ Doctor's Office/Clinic ❒ Friend ❒ Ad ❒ Community Agency ❒ Other _____

For your report complete BOTH SIDES and return by fax or mail to:

Trials Search/Community Consortium

3180 18th Street, #201, San Francisco, CA 94110

Toll-free: **1-(800) 492-5777** Phone: **(415) 476-5777** Fax: **(415) 502-8686**

E-mail: **tsearch@sfaids.ucsf.edu** Internet: **http://hivinsite.ucsf.edu/tsearch**

TS02/01/00

Trials Search Questionnaire

Date Completed: ___/___/___ (mo/day/year) **Date of Birth:** ___/___/___ (mo/day/year)

Sex: ❒ Male ❒ Female **First initial & last initial:** _____ _____

Absolute CD4 Cell Count (T-helper cells): _____ **HIV RNA Viral Load:** _____

Medical History:

Check the first column **(Past)** for each condition **you have had in the past,** but no longer have.
Check the second column **(Current)** for each medical condition that **you currently have.**

Past	Current		Past	Current	
○	❒	Anal or Genital Warts	○	❒	KS (Kaposi's sarcoma) - internal organs
○	❒	Candidiasis - Esophageal (throat)	○	❒	Lipodystrophy (Body Fat Changes)
○	❒	Candidiasis - Oral (thrush)	○	❒	Lymphoma - Hodgkin's
○	❒	Candidiasis - Vaginal (recurrent yeast infection)	○	❒	Lymphoma - Non-Hodgkin's
○	❒	Cryptococcal Meningitis	○	❒	MAC or MAI (Mycobacterium avium Complex)
○	❒	Cryptosporidiosis	○	❒	Molluscum Contagiosum
○	❒	CMV (Cytomegalovirus) - Retinitis	○	❒	Pancreatitis
○	❒	CMV - Gastrointestinal	○	❒	PCP (Pneumocystis carinii Pneumonia)
○	❒	Dementia	○	❒	Peripheral Neuropathy
○	❒	Diarrhea - HIV Related	○	❒	PID (Pelvic Inflammatory Disease)
○	❒	Hairy Leukoplakia	○	❒	PML (Progressive multifocal leukoencephalopathy)
○	❒	Hepatitis B	○	❒	Sinusitis
○	❒	Hepatitis C	○	❒	Syphilis
○	❒	Herpes Simplex Virus	○	❒	Toxoplasmosis
○	❒	Herpes Zoster Virus (shingles)	○	❒	Tuberculosis (TB)
○	❒	ITP (Immune Thrombocytopenia Purpura)	○	❒	Wasting Syndrome (unintended weight loss > 10%)
○	❒	KS (Kaposi's sarcoma) - skin and mouth	○	❒	Other:

HIV Medication History:

Check the first column **(Past)** for each medication **you have taken in the past,** but no longer take.
Check the second column **(Current)** for each medication that **you currently take.**

Past	Current		Past	Current		Past	Current	
○	❒	3TC (Epivir, lamivudine)	○	❒	Delavirdine (Rescriptor)	○	❒	Ritonavir (Norvir)
○	❒	Abacavir (Ziagen)	○	❒	Efavirenz (Sustiva)	○	❒	Saquinavir - Fortovase (soft gel)
○	❒	Amprenavir (Agenerase)	○	❒	Emtricitabine (FTC, Coviracil)	○	❒	Saquinavir - Invirase (hard Gel)
○	❒	Adefovir dipivoxil (PMEA, Preveon)	○	❒	Emivirine (MKC442, Coactinon)	○	❒	T-20 (pentafuside)
○	❒	AZT (Retrovir, Zidovudine)	○	❒	Hydroxyurea (Hydrea, Droxia)	○	❒	Tenofovir (PMPA)
○	❒	Combivir (AZT/3TC Fixed Dose Tablet)	○	❒	Indinavir (Crixivan)	○	❒	Tipranavir (PNU-140690)
○	❒	d4T (Stavudine, Zerit)	○	❒	Interleukin-2 (aldesleukin, IL-2, Proleukin)	○	❒	Trizivir (Abacavir/AZT/3TC Fixed Dose Tablet)
○	❒	ddC (zalcitabine, Hivid)	○	❒	Lopinavir (ABT-378/ritonavir)	○	❒	Vaccine (HIV)
○	❒	ddI (Didanosine, Videx)	○	❒	Nelfinavir (Viracept)			
			○	❒	Nevirapine (Viramune)			

Have Questions? Need Help? Call (415) 476-5777 (local) or 1-800-492-5777 (toll free).

About the study:

Patients are assigned by chance to one of three groups. Patients in **Group A** will take their AZT, indinavir and delavirdine three times a day. Those in Groups B and C will take their medications twice a day. Patients in **Group B** will take six pills of delavirdine twice a day while those in **Group C** will take two pills of delavirdine twice a day. All medications are pills and taken by mouth. Patients will take study medications for 24 weeks, after which they may elect to continue for an additional 24 weeks. Study visits are once a week for the first two weeks, then once a month. The study lasts 24 weeks with an additional 24-week extension.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 20,000 copies/mL
- HIV positive
- At least 14 years old

Not allowed:

- Prior use of AZT for more than one month
- Prior use of any other antiretroviral medications
- Use of any immunomodulators, such as interleukins or interferons within 21 days of study entry
- Use of any immunizations or vaccines within 21 days of study entry
- Active opportunistic infections
- Cirrhosis of the liver
- Women who are pregnant or breastfeeding
- Active alcohol and/or substance abuse which could interfere with the study

Location:

AIDS Healthcare Foundation
Research Center
Doug Bowden
(323) 913-3953

26. HIV Infection: Delavirdine, Indinavir, AZT, 3TC

Title:

M/3331/0074: An Open Label Study of Delavirdine Mesylate in Triple and Quadruple Combinations with Zidovudine, Indinavir and Lamivudine in HIV-Infected Individuals

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Delavirdine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Indinavir: antiretroviral, protease inhibitor

Purpose:

To test the safety, tolerability and effectiveness of combinations of three or four drugs.

About the study:

Patients are assigned by chance to one of four groups: delavirdine + indinavir + AZT; delavirdine + indinavir + 3TC; delavirdine + indinavir + AZT + 3TC; indinavir + AZT + 3TC. Patients in three of the groups will be taking three medications while patients in the fourth group will be taking four. Patients will know which medications they are taking. All medications are pills and taken by mouth. Study visits are once a week for the first month, then once a month for two months, then every two months. The study lasts 24 weeks and patients may choose to continue for another 24 weeks. Some locations may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: at least 50
- Viral load range: at least 20,000 copies/mL
- HIV positive
- At least 14 years old

Not allowed:

- More than six months use of AZT
- Prior use of 3TC or any NNRTIs, such as delavirdine, nevirapine, Sustiva, atevirdine, loviride or HBY 097
- Prior use of any protease inhibitors
- Use of any investigational drugs or immunomodulators, such as interferons or interleukins, within 21 days of study entry
- Use of any HIV vaccines within 21 days of study entry
- Active opportunistic infections within one month of study entry
- Use of rifampin or rifabutin within 21 days of study entry
- Use of Hismanal, Seldane, Xanax, Halcion or Propulsid within 7 days of study entry and throughout the study
- Women who are pregnant or breastfeeding
- Active alcohol or substance abuse
- Cirrhosis of the liver

Location:

UCSF Positive Health Practice
at SFGH/ICTG
Anna Smith, RN
(415) 476-9296 ext. 313

27. HIV Infection: GM-CSF, Potent Antiretroviral Therapy

Title:

ACTG A5041: The Effects of GM-CSF on Plasma HIV-1 RNA and Chemokine Receptor Expression in HIV-1 Infected Subjects Receiving Concomitant Potent Antiretroviral Therapy

Type of treatment:

GM-CSF: white blood cell stimulator

Purpose:

To see if GM-CSF affects HIV viral load. To see whether GM-CSF is safe for HIV-infected people to use for a long period of time. To see if GM-CSF can improve the immune system by increasing the number of T-cells. To see whether treatment with GM-CSF can decrease the amount of inactive HIV virus within cells that could become active in the future.

About the study:

Patients in Part 1 are assigned by chance to receive GM-CSF or placebo. GM-CSF and its placebo are given by injection under the skin three times a week for 16 weeks. Patients and/or caregivers will be taught how to give injections and dispose of needles safely. Neither patients nor their doctors will know which they are receiving for the first 16 weeks until the study ends. After 16 weeks, all patients will receive open label (real) GM-CSF by injection under the skin three times a week for an additional 32 weeks (Part 2). Study visits are at Weeks 4, 8, 16, 20, 24, 32, 40 and 48. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 1,500 copies/mL
- HIV positive
- At least 18 years old
- Stable (no changes) potent antiretroviral therapy for at least eight weeks prior to study entry and for at least the first 16 weeks of the study. Potent antiretroviral therapy is defined as a minimum of three drugs that includes any of the following:
  -2 NRTIs and an NNRTI;
  -2 NRTIs and abacavir;
  -2 NRTIs and a protease inhibitor;
  -2 protease inhibitors and an NNRTI;
  -2 protease inhibitors and an NRTI;
  -an NRTI, an NNRTI and a protease inhibitor

Not allowed:

- Infections or other acute illnesses within 14 days of study entry
- Women who are pregnant or breastfeeding
- Documented or suspected acute hepatitis within 30 days of study entry
- Any cancers other than KS of the skin (five or less lesions)
- Use of chemotherapy or radiation within 14 days of study entry
- Unexplained fever >38.5 C (101 F) for any seven consecutive days, or chronic diarrhea defined as more than three liquid stools per day persisting for 15 days, within 30 days of study entry
- Significant cardiopulmonary disease including congestive heart failure or significant cardiac arrhythmia
- Use of any immunomodulators, such as interferons, interleukins, thalidomide, HIV vaccines, or corticosteroids within 30 days of study entry

Part 2

- Patients who experienced a > 1.0 $\log_{10}$ increase in HIV viral load while on Part 1
- Patients who experienced a >50% decrease in T-cells during Part 1

Location:

Marin County Specialty Clinic
Joann Volinski, RN
(415) 499-7377

Stanford University Medical Center
Sandra Valle, PA-C
(650) 723-8169

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

28. HIV Infection: HE2000 (DHEA Analog)

Title:

HE2000-005: A Phase I/II, Open-Label Study of the Safety, Tolerance, Pharmacokientics, Drug-Interaction and Anti-HIV Activity of Intramuscularly Administered Alpha-Epi-Br (HE2000) in HIV-Infected Patients on Salvage Therapy

Type of treatment:

HE2000: immune modulator

Purpose:

To see if HE2000 is safe, well-tolerated and effective in lowering the amount of HIV in the blood of patients who are failing at least their second HAART treatment. To see how HE2000 is processed by the body and to see how it interacts with other HIV medications. HE2000 is a DHEA analogue.

About the study:

This is a dose-ranging or dose-escalating study. This means that the first group of patients will receive the lowest dose of HE2000. If no bad side effects are seen, the next group of patients will receive a higher dose and so forth until the highest dose researchers plan to study has been given or the highest dose that does not cause bad side

effects has been found. There are two parts to this study. Part A is a single injection of HE2000. HE2000 is given by injection into a mucsle. Part B consists of five consecutive daily injections of HE2000. Patients will receive the same dose of HE2000 throughout both Parts A and B of the study. There are multiple study visits during the first five weeks of the study, then montly study visits.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: between 5,000 and 250,000 copies/mL
- HIV positive
- At least 18 years old
- Patients must be having poor response to at least their second HAART treatment
- Willing to make no changes to antiretroviral treatments throughout this study

Not allowed:

- Active opportunistic infections
- Co-infection with hepatitis B and/or C
- Any cancers requiring chemotherapy within four weeks of study entry
- Use of any immunomodulators, such as interleukins or interferons, within four weeks of study entry
- Use of metabolic inhibitors, such as hydroxyurea, within four weeks of study entry
- Women who are pregnant or breastfeeding
- G6PD deficiency
- Patients using testosterone

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

29. HIV Infection: Highly Active Antiretroviral Therapy (HAART)

Title:

CPCRA 058: FIRST Study: A Randomized, Open-Label Study of the Long-Term Effectiveness of Three Initial Highly Active Antiretroviral Therapy (HAART) Strategies in HAART-Naive, HIV-Infected Persons

Type of treatment:

HAART: antiretrovirals, including at least one protease inhibitor

Purpose:

To see if it is best to start antiretroviral therapy with a protease inhibitor-containing combination, an NNRTI-containing combination (such as nevirapine or Sustiva), or a protease inhibitor plus an NNRTI-containing combination. These three strategies will be studied for their long-term effectiveness and safety.

About the study:

Patients are assigned by chance to one of three groups. The first group will take one or two protease inhibitors plus two NRTIs (such as AZT, ddI, ddC, 3TC or d4T). The second group will take an NNRTI plus 2 NRTIs. The third group will take one or two protease inhibitors, one NNRTI and one or two NRTIs. Patients will know to which group they have been assigned. Patients and their doctors also have the option to choose their own study medications or to be assigned by chance to receive study-specific medications. Study visits are at Month 1, Month 4 and every four months thereafter until the study ends. This study does not supply any study medications. All medications must be obtained by prescription or by other means. The study will last about five years.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 13 years old
- Patients choosing to take the Invirase form of saquinavir must also take ritonavir

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of any protease inhibitors or NNRTIs
- More than four weeks cummulative use of any NRTI (except 3TC) **or** more than one week use of 3TC

Location:

Castro-Mission Health Center
Mike Jones, RN
(415) 476-9554 ext. 35

Milton Estes, MD
Mike Jones, RN
(415) 476-9554 ext. 35

Robert C. Scott, MD
Paula Pell, RN, MS
(415) 476-9554 ext. 24

San Francisco VA Medical Center
Sherrill Crawford, RN
(415) 476-9554 ext. 14

UCSF Positive Health Practice
at Parnassus
Jane Pannell, RN
(415) 476-9554 ext. 23

UCSF Positive Health Practice at SFGH
Jane Pannell, RN
(415) 476-9554 ext. 23

William F. Owen Jr., MD
Sherrill Crawford, RN
(415) 476-9554 ext. 14

30. HIV Infection: Hydroxychloroquine, Hydroxyurea, ddI

Title:

An Open Label Phase I/II Study of the Safety and Antiviral Efficacy of Hydroxychloroquine in Combination with Hydroxyurea and Videx (ddI or Didanosine) in HIV-1 Infected Patients

Type of treatment:

Hydroxychloroquine: antimalarial
Hydroxyurea: cellular inhibitor
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To examine the short-term (two months) and long-term (eight months) safety, tolerability and antiviral effectiveness of the combination of hydroxychloroquine, hydroxyurea and ddI in HIV infected patients.

About the study:

All patients will receive all three drugs in combination for eight weeks. Patients will know which drugs they are taking; there are no placebos in this study. All medications are pills and taken by mouth twice a day. Patients who have received some benefit (as indicated by a reduction in viral load or an increase in T-cell counts) from the study medications will be permitted to enter an extension study for an additional 24 weeks. Study visits are once a month and eye exams will be performed at screening, Week 8 and following the extension phase (Week 32, if applicable). There are three groups of patients to be enrolled in this study. Please see the eligibility criteria listed below.

Required:

- HIV positive
- At least 18 years old
- No antiretroviral therapy for eight weeks preceeding study entry

GROUP A:

- CD4 cell (T-cell) range: more than 200
- Viral load range: between 5,000 and 80,000 copies/mL
- Six months or less experience with antiretroviral medications
- No previous ddI therapy

GROUP B:

- CD4 cell (T-cell) range: more than 100
- Viral load range: between 5,000 and 1,000,000 copies/mL
- No ddI therapy within the past year

GROUP C:

- CD4 cell (T-cell) range: more than 200
- Viral load range: between 5,000 and 250,000 copies/mL
- No ddI therapy within the past year

Not allowed:

- Active opportunistic infections
- Previous use of the combination of ddI and hydroxyurea
- Impaired visual function, including previous CMV retinitis
- Women who are pregnant or breastfeeding

Location:

AIDS Research Alliance
Corie Castro
(310) 358-2429

New

31. HIV Infection: Hydroxyurea, Efavirenz, ddI, d4T

Title:

BMS 005: Open-Label, Randomized, Observational Pilot Study of Hydroxyurea When Used With Stavudine + Didanosine + Efavirenz Versus the Delayed Addition of Hydroxyurea to Stavudine + Efavirenz in Protease Inhibitor-Experienced and Non-Nucleoside Reverse Transcriptase Inhibitor Naive Subjects

Type of treatment:

Hydroxyurea: cellular inhibitor
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if adding hydroxyurea to ddI, d4T and efavirenz (Sustiva) is safe and effective in lowering the amount of HIV in the blood.

About the study:

All patients will take efavirenz, ddI, d4T and are assigned by chance to add hydroxyurea for eight weeks. After eight weeks, those patients who were not assigned to add hydroxyurea will now add it. All medications are pills and taken by mouth. There are no placebos in this study. Study visits are once a month and the study lasts one year.

Required:

- CD4 cell (T-cell) range: more than 200
- Viral load range: more than 5,000 copies/mL
- HIV positive
- At least 18 years old

- Must have prior use of at least one protease inhibitor
- Must have no experience with either ddI **or** d4T

Not allowed:

- Prior use of any NNRTIs, such as delavirdine, nevirapine or Sustiva
- Women who are pregnant or breastfeeding
- Active opportunistic infections
- Patients who have past experience with both ddI **and** d4T

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

32. HIV Infection: Hydroxyurea, ddI, d4T

Title:

RIGHT 702: A Phase I/II Study of the Safety and Antiretroviral Activity of Nine Hydroxyurea Regimens in Combination with ddI and d4T

Type of treatment:

Hydroxyurea: cellular inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To observe and compare different doses of hydroxyurea combined with ddI and d4T for safety and tolerability in HIV-infected patients.

About the study:

All patients will take ddI and d4T and are assigned by chance to receive one of nine different doses of hydroxyurea. Patients will know which dose they are taking. All medications are pills and taken by mouth. Study visits are every two weeks for the first month, then once a month. The study lasts for 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: between 5,000 and 100,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- Past or current AIDS-defining opportunistic infections
- Prior use of hydroxyurea
- Prior use of any protease inhibitor
- Any cancers requiring chemotherapy within the next 24 weeks
- Women who are pregnant or breastfeeding
- Use of any immunomodulators (such as interferons or interleukins) or HIV vaccines within 30 days of study entry
- Current alcohol and/or substance abuse
- Transfusion of red blood cells within 60 days of study entry or a history of transfusion-dependent anemia
- Use of erythropoietin, G-CSF or GM-CSF within 60 days of study entry

Location:

AIDS Healthcare Foundation
Research Center
Bonnie Oamar
(323) 913-3953

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, ext. 3763

33. HIV Infection: Indinavir, Ritonavir

Title:

M98-985: Norvir (Ritonavir)/Indinavir Intensification Therapy for Subjects with Low Plasma Viremia

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To see if it is safe and effective to add ritonavir to patients who are currently being treated with triple combination therapy which includes indinavir.

About the study:

All patients will add ritonavir to their triple combination therapy which includes indinavir plus two NRTIs, such as AZT, ddI, ddC, 3TC or d4T. Ritonavir is a liquid and taken by mouth twice a day. Study visits are every three weeks for the first four months, then every two months. The study lasts 48 weeks. Medications are **not** provided by this study; patients will need to obtain medications by prescription or by other means.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: between 50 and 50,000 copies/mL
- HIV positive
- At least 18 years old
- Must currently be taking indinavir plus two NRTIs

Not allowed:

- Use of any other protease inhibitors except indinavir for at least three months prior to study entry
- Prior use of ritonavir
- Women who are pregnant or breastfeeding

Location:

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

New

34. HIV Infection: Indinavir, Ritonavir

Title:

Merck 088-00: A Multicenter, Open-Label, 24-Week Study to Evaluate the Safety and Activity of Indinavir Sulfate 800 mg b.i.d. in Combination With Ritonavir 200 mg b.i.d and Two NRTIs in HIV-1 Infected Patients Who Failed PI Therapy

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To see if the combination of indinavir and ritonavir is capable of producing higher drug levels in the blood and in slowing the development of drug-resistant HIV virus for HIV-infected patients who have failed protease inhibitor therapy.

About the study:

All patients will take indinavir and ritonavir plus two NRTIs (such as AZT, ddC, ddI, d4T, 3TC or abacavir), one of which must be new to the patient. Indinavir and ritonavir are pills and taken twice day for 24 weeks. Study visits are once a month and the study lasts 24 weeks. The study will not supply the NRTI medications. Patients must obtain them by prescription or by other means.

Required:

- CD4 cell (T-cell) range: at least 100
- Viral load range: at least 2,500 copies/mL
- HIV positive
- At least 18 years old
- Must be on an antiretroviral treatment that includes a licensed protease inhibitor for at least 16 weeks prior to study entry
- Must discontinue any NNRTI (delavirdine, nevirapine, efavirenz) therapy two weeks prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Patients in whom no new NRTI therapy is possible
- Prior use (defined as seven days or more) of dual protease inhibitor therapy
- Active hepatitis
- More than 24 weeks time between initial protease inhibitor failure and study entry
- Current use of investigational drugs, immunomodulators (interleukins, interferons) or chemotherapy

Location:

University of Southern California ACTU
Irene Teran, RN
(323) 343-8285

New

35. HIV Infection: Indinavir, Ritonavir, d4T, 3TC

Title:

Merck 094-01: A Multicenter, Open-Label, 24-Week Pilot Study to Evaluate the Safety and Efficacy of Indinavir Sulfate 800 mg bid in Combination with Ritonavir 100 mg/d4T/3TC bid in HIV-Infected Individuals

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if it is safe and effective to add indinavir to the combination of ritonavir, d4T and 3TC, in lowering the amount of HIV in the blood.

About the study:

All patients will receive indinavir (Crixivan), ritonavir (Norvir), d4T and 3TC. There are no placebos in this study. All medications except ritonavir are pills and taken by mouth twice a day; ritonavir is supplied in liquid form. Study visits are once a month and the study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: at least 75
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 18 years old
- Willing to discontinue all antiretroviral medications that are unrelated to the study

Not allowed:

- Active opportunistic infections or malignancies
- Prior use of 3TC, abacavir, or any protease inhibitors
- Use of any investigational medications
- Use or anticipated use of chemotherapy for cancers during treatment in the study
- Women who are pregnant or breastfeeding

Location:

Institute for HIV Research,
CPMC - Davies Campus
Steve Collinson, RN
(415) 600-6660

Kaiser Permanenté Clinical Trials Unit,
San Francisco
Mary Beth Charland, RN
(415) 202-3480

UCSF Positive Health Practice
at SFGH/ICTG
Doug Raggett, RN
(415) 476-9296 ext. 312

36. HIV Infection: Interleukin-2, HAART

Title:

CS-L2-9901 (SILCAAT): A Phase III Multicenter Randomized Study of the Biological and Clinical Efficacy of Subcutaneous Recombinant, Human Interleukin-2 in HIV-Infected Patients with Low CD4+ Counts Under Active Antiretroviral Therapy

Type of treatment:

HAART: antiretrovirals, including at least one protease inhibitor
Interleukin-2: immune modulator

Purpose:

To see if interleukin-2, also called Proleukin, combined with Highly Active Antiretroviral Therapy (HAART) leads to a decreased rate of HIV disease progression.

About the study:

Patients are assigned by chance to receive interleukin-2 or to continue taking their current antiretroviral medications. Those patients assigned to take interleukin-2 will receive injections under the skin twice a day for five consecutive days every eight weeks plus continue with their current antiretroviral medications. Patients will know which medications they are taking; there are no placebos in this study. Study visits are every two months for the first year, then every four months. The study will last from four to six years.

Required:

- CD4 cell (T-cell) range: between 50 and 300
- Viral load range: less than 10,000 copies/mL
- HIV positive
- At least 18 years old
- Stable (no changes) antiretroviral therapy with three or more medications for at least six months prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Active AIDS-defining illnesses
- Current use of hydroxyurea
- Any cancers
- Active alcohol and/or substance abuse

Location:

ACRC
Michele Downing, RN
(650) 364-6563

HIVCare,
Saint Francis Memorial Hospital
Mark Bowers
(415) 353-6215

Harbor-UCLA Medical Center
Petra Miller, RN
(310) 222-3848

Kaiser Permanente - Los Angeles
Rosa Kawahira, RN
(323) 783-8172

Kaiser Permanente Clinical Trials Unit,
San Francisco
Mary Beth Charland, RN
(415) 202-3480

Orange Coast Medical
Charles Walworth, MD
(949) 646-1111

Santa Clara Valley Medical Center
Carol Kemper, MD
(408) 885-4690

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF Positive Health Practice
at SFGH/ICTG
Rosaleen Brennan, RN
(415) 476-9296 ext. 314

37. HIV Infection: Interleukin-2, HAART

Title:

ACTG A5051: Treatment Rollover for Subjects Formerly on ACTG 328 With Subcutaneous Interleukin-2 (IL-2) in Combination With Highly Active Antiretroviral Therapy (HAART)

Type of treatment:

HAART: antiretrovirals, including at least one protease inhibitor
Interleukin-2: immune modulator

Purpose:

To determine the long-term safety, tolerance and effectiveness of interleukin-2 in combination with HAART **for patients who participated in ACTG 328.**

About the study:

Eligible patients will be assigned to either Step I or Step II of this study depending on viral load measurements. Patients may have the option of changing their HAART medications and starting Step I **or** staying on their current HAART medications and adding interleukin-2 (Step II), depending on viral load measurements, their T-cell counts, and to which treatment group they were assigned for ACTG 328. Patients on Step I will take HAART medications and have study visits at Weeks 4, 8 and 12. Patients may stay on Step I for a maximum of 12 weeks and may proceeed to Step II at any time after Week 4, depending on T-cells and viral load measurements. Patients enrolled in Step II will take HAART medications and receive interleukin-2 injections twice a day for five consecutive days (one cycle). Interleukin-2 is given by injection under the skin and patients will be taught how to give themselves injections. The interleukin-2 cycles will be repeated every 8-24 weeks for 3-9 cycles. The length between and number of cycles will depend on T-cell counts. Study visits on Step II will be on the day of the first injection of each cycle, and five days and possibly 30 days after the first injection of each cycle. Patients on Step II will also have study visits every two months for T-cell counts. The study lasts no longer than 84 weeks.

Required:

- Must have completed at least 84 weeks **on** treatment **on** study of ACTG 328

Step II

- Patients previously taking interleukin-2 during ACTG 328 must have had a 25% or greater increase in T-cells from their Week 11 T-cell count by Weeks 60 or 72 of ACTG 328, **and** a viral load of less than 5,000 copies/mL
- Patients previously assigned to the HAART-only group of ACTG 328 must have HIV viral load of less than 5,000 copies/mL

Not allowed:

- Use of any other immunomodulators (such as corticosteroids, interferons, thalidomide, GM-CSF, or DNCB) within four weeks of study entry
- Patients requiring treatment for active cardiac disease
- Any cancers requiring systemic chemotherapy
- Women who are pregnant or breastfeeding
- Untreated thyroid disease
- Use of rifampin or rifabutin within seven days prior to study entry
- Active alcohol and/or substance abuse which could interfere with the study

Location:

Stanford University Medical Center
Sandra Valle, PA-C
(650) 723-8169

New

38. HIV Infection: Interleukin-2, HAART

Title:

CS-MM-9901: A Bridging Dose-Escalation Study of the Safety, Pharmacokinetic Properties, and Immunologic Effect of Subcutaneous L2-7001 (Recombinant Human Interleukin-2) in Patients Infected with HIV with $CD4^+$ T-Cell Counts of 300-500 cells/mm^3 and Viral Burden Under 10,000 copies/mL on Active Antiretroviral Therapy (ART)

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To see which of three different doses of L2-7001 (a new formulation of interleukin-2) is best when combined with antiretroviral therapy and compared to proleukin (a different form of interleukin-2).

About the study:

Patients are assigned by chance to receive one of three doses of L2-7001 along with their antiretroviral therapy or to receive proleukin with their antiretroviral therapy or to continue taking antiretoviral therapy by itself. L2-7001 and proleukin are given by injection under the skin every twelve hours for the first five days of an eight-week cycle. There are three cycles. There are from six to nine study visits required per cycle and a final follow-up visit for a total of 22 visits over 32 weeks. Patients completing this study will be eligible to be screened for enrollment in a compassionate use study using L2-7001.

Required:

- CD4 cell (T-cell) range: between 300 and 500
- Viral load range: less than 10,000 copies/mL
- HIV positive
- At least 18 years old
- Stable (no changes) antiretroviral therapy for at least four months prior to study entry. Therapy must consist of at least two drugs, one of which is a protease inhibitor

Not allowed:

- Active opportunistic infections
- Prior use of interleukin-2
- Women who are pregnant or breastfeeding
- Use of hydroxyurea within four months of study entry
- Cancers requiring chemotherapy
- Uncontrolled diabetes or high blood pressure
- Psychiatric illnesses or active substance abuse which could interfere with the study
- Use of any immunomodulators (such as interferons, interleukin or corticosteroids) within four weeks of study entry

Location:

Kaiser Permanente Clinical Trials Unit, San Francisco
Mary Beth Charland, RN
(415) 202-3480

39. HIV Infection: Marijuana, Marinol

Title:

CC038/GCRC531: Short Term Effects of Cannabinoids in HIV Patients

Type of treatment:

Dronabinol: appetite stimulant
Marijuana: cannabinoid

Purpose:

To see if the interaction between cannabinoids and indinavir or nelfinavir can alter HIV RNA viral load. To measure the short-term effects of smoked marijuana on appetite, energy and body composition and body weight.

About the study:

Patients are admitted to the Research Center at San Francisco General Hospital for an initial four-day lead in period. During this time, patients will become accustomed to the Research Center and baseline measurements, such as T-cell counts, viral load, testosterone levels, expired carbon monoxide and body composition, will be obtained. Patients will then be asked if they wish to continue in the study. If so, patients are assigned by chance to receive marijuana cigarettes, marinol pills or placebo. Patients will not know if they are receiving marinol or placebo until the study ends. Marijuana cigarettes are smoked three times a day. Marinol and its placebo are pills and taken by mouth three times a day. Patients will spend a total of 25 days and nights in the Research Center. The baseline measurements taken during the first four days will be repeated throughout the course of the hospital stay. After being discharged from the Research Center, patients will have two outpatient visits, one nine days after and the other three weeks after discharge from the hospital. **Patients will be paid $1,000 for completing the study** (or $20 per night if not completed).

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: must be stable (no drastic changes) for at least eight weeks prior to study entry
- Stable (no changes) antiretroviral medications for at least eight weeks
- Must have used marijuana in the past
- Must be taking indinavir (Crixivan) or nelfinavir (Viracept)

Not allowed:

- Active opportunistic infections or cancers requiring acute treatment
- Unintentional weight loss of more than 10% of body weight during the past six months
- Use of megace, nandrolone, oxandrolone, oxymetholone, DHEA, growth hormone, thalidomide, prednisone, interleukin-2, chemotherapy, radiation, other anabolic steroids or investigational agents within eight weeks of study entry
- Active alcohol and/or substance abuse
- Methadone maintenance
- Use of tobacco within 30 days of study entry
- Use of smoked marijuana within 30 days of study entry
- Pulmonary complications, such as asthma, tuberculosis, emphysema, cancer
- AIDS Dementia Complex (Stage II or higher)
- Women who are pregnant or breastfeeding

Location:

Community Consortium
Roz Leiser, RN
(415) 502-5705

40. HIV Infection: Observational

Title:

CPCRA 060: A Prospective Study of Long-Term Clinical, Virologic, and Immunologic Outcomes in HIV-Infected Individuals

Type of treatment:

Observational: none

Purpose:

To provide long-term monitoring of HIV-infected patients who have taken part in certain CPCRA trials (qualifying studies) and people who have little or no treatment for HIV.

About the study:

Patients will have information collected from their medical record every four months. This information will include illnesses patients have had and medications they have taken. If this information is not available from the medical record, a study nurse may contact patients by phone and ask them to schedule a clinic visit. T-cell counts and HIV viral load values will also be collected. Patients will be in this study for up to five years.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Either antiretroviral naive, defined as no previous protease inhibitor or NNRTI use, one week or less use of 3TC and four weeks or less of NRTI treatments **or** currently or previously enrolled in a qualifying CPCRA trial

Not allowed:

- No exclusions

Location:

Castro-Mission Health Center
Mike Jones, RN
(415) 476-9554 ext. 35

East Bay AIDS Center
Paula Pell, RN, MS
(415) 476-9554 ext. 24

Milton Estes, MD
Mike Jones, RN
(415) 476-9554 ext. 35

Robert C. Scott, MD
Paula Pell, RN, MS
(415) 476-9554 ext. 24

San Francisco VA Medical Center
Sherrill Crawford, RN
(415) 476-9554 ext. 14

UCSF Positive Health Practice at Parnassus
Jane Pannell, RN
(415) 476-9554 ext. 23

UCSF Positive Health Practice at SFGH
Jane Pannell, RN
(415) 476-9554 ext. 23

William F. Owen Jr., MD
Sherrill Crawford, RN
(415) 476-9554 ext. 14

41. HIV Infection: Observational

Title:

CC 045: A Prospective, Longitudinal, Community-Based Observational Study of HIV-Infected Individuals: The Community Consortium Observational Cohort Study (CC-OCS)

Type of treatment:

Observational: none

Purpose:

The purpose of this study is to more clearly understand the role of various drug treatments used in reducing patients' HIV viral load levels. This information maybe helpful in designing the most beneficial drug treatments.

About the study:

This is a data collection study and patients will have their medical record reviewed every four to six months to collect data such as CD4 cell (T-cell) counts, HIV viral load, new illnesses and medications. During regularly-scheduled doctor visits, a research nurse may ask questions about medications about current health and medications. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old

Not allowed:

- Patients planning to move away from the Bay Area

Location:

Castro-Mission Health Center
Mike Jones, RN
(415) 476-9554 ext. 35

East Bay AIDS Center
Paula Pell, RN, MS
(415) 476-9554 ext. 24

Milton Estes, MD
Mike Jones, RN
(415) 476-9554 ext. 35

Mission Neighborhood Health Center
Mike Jones, RN
(415) 476-9554 ext. 35

Robert C. Scott, MD
Paula Pell, RN, MS
(415) 476-9554 ext. 24

San Francisco VA Medical Center
Sherrill Crawford, RN
(415) 476-9554 ext. 14

42. HIV Infection: PMPA Prodrug (Tenofovir Disoproxil)

Title:

GS-99-907: A Phase III, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study of the Safety and Efficacy of Tenofovir Disoproxil Fumarate in Combination With Other Antiretroviral Agents for the Treatment of HIV-Infected Patients

Type of treatment:

PMPA Prodrug: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To evaluate the antiviral activity of two dose levels of once daily PMPA Prodrug (tenofovir) when added to stable antiretroviral therapy in HIV-infected patients.

About the study:

Patients are assigned by chance to receive one of two doses of PMPA Prodrug (tenofovir) or to receive a placebo. Neither patients nor their doctors will know which they are taking until the study ends. After 24 weeks, those patients assigned to take placebo or to take the lower dose of tenofovir will be switched to the higher dose of tenofovir. Study visits are once a month and the study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 400 but less than 10,000 copies/mL
- HIV positive
- Between 18 and 65 years old
- On stable (no changes) antiretroviral therapy of no more than four drugs for at least eight weeks

Not allowed:

- Prior use of tenofovir or adefovir dipivoxil (Preveon)
- Any new AIDS-defining illness within 30 days prior to study entry
- Any immunizations within 30 days prior to study entry
- Women who are pregnant or breastfeeding
- Any cancers other than KS of the skin or basal cell carcinoma
- Significant kidney or bone disease
- Active alcohol and/or substance abuse which could interfere with the study

Location:

Harbor-UCLA Medical Center
Dena Duran, LVN
(310) 222-3848

Kaiser Permanente - Los Angeles
Mitzi St. Ange, RN
(323) 783-8959

Kaiser Permanente Clinical Trials Unit, San Francisco
Anna Dowling, RN
(415) 202-3487

Pacific Horizon Medical Group
Jennifer Armfield
(415) 292-5481

San Francisco VA Medical Center
Sandy Charles, RN
(415) 221-4810, ext. 3763

New

43. HIV Infection: Remune, Nelfinavir, Combivir

Title:

AG1661-202: A Randomized, Double-Blind, Adjuvant-Controlled, Multicenter, Phase III Study to Compare the Virologic and Immunologic Effect of Highly Active Antiretroviral Therapy (HAART) Plus Remune Versus HAART Plus Incomplete Freund's Adjuvant (IFA) in Antiretroviral-Naive Patients Infected With Human Immunodeficiency Virus Type 1 (HIV-1)

Type of treatment:

Combivir: antiretroviral, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
Remune: immune modulator

Purpose:

To see if adding Remune to Highly Active Antiretroviral Therapy (HAART) is more effective in reducing and maintaining the viral load to an undetectable level.

About the study:

All patients will begin therapy with nelfinavir (Viracept) and Combivir (a fixed-dose tablet of AZT and 3TC). After eight weeks, those patients who have a viral load of more than 2,000 copies/mL will discontinue the study. Patients with a viral load of 2,000 copies/mL or less will be assigned by chance to receive Remune or placebo. Remune and its placebo are given by injection into a muscle starting at Week 9 and again every 12 weeks. Study visits are once a month and the study lasts at least 48 weeks. Patients who complete this study will be eligible to participate in another Remune study.

Required:

- CD4 cell (T-cell) range: at least 250
- Viral load range: at least 10,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Use of any investigational drugs or immune-base therapy (such as interleukins or interferons) within 30 days of study entry
- Any immunizations within six weeks of study entry
- Prior use of Remune
- Any cancers requiring chemotherapy

Location:

AIDS Research Alliance
Corie Castro
(310) 358-2429

Kaiser Permanente Clinical Trials Unit, San Francisco
Delfino Martinez, RN
(415) 202-3480

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

44. HIV Infection: RevM10 (Gene Therapy)

Title:

104: A Study of Infused RevM10 Enhanced Blood Stem Cells (REVM10-HSC) in HIV-Infected Subjects Who Have Been Mobilized with G-CSF (simplified)

Type of treatment:

REVM 10: gene therapy

Purpose:

To see if it is safe and effective to give genetically altered blood cells with or without cyclophosphamide to patients in various stages of HIV infection.

About the study:

All patients will receive injections of G-CSF (Neupogen) under the skin for four days, followed by apheresis on the fifth day. Apheresis is a process by which blood is removed from the body from one arm, certain cells (called stem cells) are separated from the blood, and the remaining blood is returned to the body through a vein in the other arm. The RevM10 gene is then added to the stem cells and the genetically-altered stem cells are returned to the patient by infusion into a vein. There are two groups in this study. The first group of patients will receive the altered stem cells without the addition of cyclophosphamide, also called Cytoxan. Cytoxan is believed to enable to altered stem cells to get into the bone marrow. If no bad side effects are seen in the first group, the second group of patients will receive an infusion of Cytoxan 48 hours prior to the infusion of their genetically-altered stem cells. Patients will be paid for their participation in this study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Patients on antiretroviral therapy must be on stable (no changes) doses for at least 30 days prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Past or current cancers
- Use of G-CSF, GM-CSF, interleukins, interferons, growth hormones or steroids within 30 days of study entry
- Any pheresis procedure within 90 days of study entry
- Treatment for opportunistic infections within 30 days prior to study entry
- Active alcohol and/or substance abuse
- Use of any investigational drug within 30 days of study entry

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

45. HIV Infection: Ritonavir, Fortovase, Sustiva, Nelfinavir, Indinavir

Title:

CPCRA 057: PIP Study: A Randomized Study of the Virologic Efficacy of Different Antiretroviral (AR) Treatment Strategies in HIV-Infected Inividuals With Detectable Plasma HIV RNA Measurements After At Least 16 Weeks on Their Initial Protease Inhibitor-Containing AR Regimens

Type of treatment:

Fortovase: antiretroviral, protease inhibitor
Indinavir: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)

Purpose:

To compare different treatments for HIV infection to see which works best to lower the amount of HIV and raise the number of T-cells in the blood after at least 16 weeks on their first anti-HIV therapy.

About the study:

There are two options in this study and before beginning this study, patients and their doctors will decide which option is best for them. **Option 1** is for patients who have not taken many NRTIs (such as AZT, ddI, ddC, 3TC or d4T) and still have two or more that can be taken with the study drugs. **Option 2** is for patients who have already taken most NRTIs and now have only one treatment choice that can be taken with study drugs. In this study, these NRTIs are called backround drugs. Patients who enter Option 1 will switch to Fortovase (soft gel saquinavir) plus ritonavir plus backround medication. They are further assigned by chance to add or not add Sustiva (efavirenz). Patients entering into Option 2 who are currently taking nelfinavir will be assigned by chance to receive indinavir plus Sustiva plus backround medications OR to receive Fortovase plus ritonavir plus Sustiva plus backround medications. Those patients in Option 2 who are currently taking indinavir or ritonavir will be assigned by chance to receive nelfinavir plus Sustiva plus backround medications OR to receive Fortovase plus ritonavir plus Sustiva plus backround medications. All patients will know which medications they are receiving. Patients will take their assigned drugs for one year. If at any time after taking study medications for eight weeks, patients do not achieve a low enough HIV viral load, they will have the opportunity to switch medications. Study visits are at Months 1, 2, 4, 8 and 12. The study lasts one year. Medications for this study are not supplied by the study. Patients must obtain all study medications by prescription.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 400 copies/mL by Roche PCR
- HIV positive
- At least 13 years old
- On antiretroviral treatment consisting of at least two NRTIs plus a protease inhibitor (nelfinavir, indinavir or ritonavir) for at least 16 consecutive weeks
- Planned change in antiretroviral treatment because of a detectable HIV RNA level after 16 weeks of the initial protease inhibitor-containing treatment

Option 1

- Must be at least two NRTIs (or other drugs with anti-HIV activity) to which patients have not been exposed, to be used as backround therapy

Option 2

- Must be at least one NRTI or other drug with anti-HIV activity available (not required to be new) to be used for backround therapy

Not allowed:

- Use of any protease inhibitors other than nelfinavir, indinavir or ritonavir for more than two weeks
- Use of any NNRTIs, such as nevirapine, delavirdine or Sustiva for more than one week
- Any vaccination within two weeks prior to obtaining the blood specimen for the screening or randomization HIV RNA measurement
- Active opportunistic infections
- More than two weeks use of nelfinavir for patients who are failing indinavir/ritonavir treatment **or** more than two weeks use of indinavir/ritonavir for patients who are failing nelfinavir treatment
- Women who are pregnant or breatstfeeding

Location:

Castro-Mission Health Center
Mike Jones, RN
(415) 476-9554 ext. 35

Kaiser Permanente Clinical Trials Unit, San Francisco
Delfino Martinez, RN
(415) 202-3480

Milton Estes, MD
Mike Jones, RN
(415) 476-9554 ext. 35

Robert C. Scott, MD
Paula Pell, RN, MS
(415) 476-9554 ext. 24

San Francisco VA Medical Center
Sherrill Crawford, RN
(415) 476-9554 ext. 14

UCSF Positive Health Practice at Parnassus
Jane Pannell, RN
(415) 476-9554 ext. 23

UCSF Positive Health Practice at SFGH
Jane Pannell, RN
(415) 476-9554 ext. 23

William F. Owen Jr., MD
Sherrill Crawford, RN
(415) 476-9554 ext. 14

46. HIV Infection: Ritonavir, Indinavir

Title:

M99-047: The Norvir/Indinavir Combination Evaluation Study: A Randomized, Controlled, Open-Label Comparison of Continuing Indinavir Q8H vs. Switching to Norvir/Indinavir 400 mg/400 mg/BID (The NICE Study)

Type of treatment:

Indinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To study the medication-taking habits and preference of HIV-infected patients taking indinavir and ritonavir twice a day compared to taking indinavir three times a day. To see if these two treatments are safe, well-tolerated and effective in maintaining undetectable HIV viral load when combined with two NRTIs.

About the study:

Patients are assigned by chance to take indinavir and ritonavir twice a day along with their current NRTIs (AZT, ddI, ddC, 3TC, d4T, abacavir) or to continue taking their current antiretroviral therapy, which includes indinavir three times a day. All patients will know which treatments they are receiving. Study visits are once a month and the study lasts for 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: undetectable
- HIV positive
- At least 18 years old
- Must be taking indinavir 800 mg every eight hours along with two NRTIs

Not allowed:

- Women who are pregnant or breastfeeding
- Use of any investigational drug within 30 days of study entry

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

East Bay AIDS Center
Lucinda Hopewell, PA-C
(510) 204-4109

St. Luke Medical Group & Clinical Trials
Ida Proctor
(619) 235-0501

47. HIV Infection: Sustiva (efavirenz), Abacavir, Indinavir, 3TC, ddI, d4T

Title:

DMP 266-053: A Phase III Multicenter, Open-Label Study to Compare Antiretroviral Activity, Tolerability, and Safety of Three Regimens (Efavirenz + Stavudine + Didanosine, Abacavir + NRTI + Lamivudine, Stavudine + Didanosine + Indinavir) in HIV-Infected Patients **-A Rollover Study for DMP 266-006**

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare the safety, tolerability and effectiveness of three antiretroviral combinations for patients who have failed antiretroviral treatments in study DMP 266-006.

About the study:

Patients from DMP 266-006 are rolled over to one of three antiretroviral drug combinations. **Group 1** will receive efavirenz (Sustiva), d4T and ddI. **Group 2** will receive abacavir (Ziagen), 3TC and another NRTI, such as AZT, ddI, d4T, or ddC. **Group 3** will receive indinavir, d4T and ddI. All medications are pills and taken by mouth and patients will know which medications they are receiving. Study visits are once a month and the study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: a rise above 400 copies/ml on two occasions after reaching a lowest amount of less than 400 copies/mL on two consecutive occasions **or** HIV viral load level that never drops below 400 copies/mL by 24 weeks on DMP 266-006 **or** a rise of 0.75 $\log_{10}$ or more on two consectuive occasions relative to the lowest HIV viral load if the viral load never dropped below 400 copies/mL
- Assigned to one of the three treatment groups in DMP 266-006 and maintained that treatment prior to enrolling in this study
- Between 13 and 60 years old

Not allowed:

- Severe peripheral neuropathy
- Active or chronic hepatitis
- Prior use of any other experimental medication
- Any vaccination within three weeks of study entry
- Chemotherapy within three months or the need for such throughout the study
- Active opportunistic infections

- Moderate to severe diarrhea or vomiting lasting more than four days within three months of study entry
- Women who are pregnant or breastfeeding
- Active alcohol and/or substance abuse which would interfere with the study

Location:

Orange Coast Medical
Charles Walworth, MD
(949) 646-1111

48. HIV Infection: Sustiva, Nelfinavir, ddI, d4T

Title:

AEHIV 003: A Phase II, Randomized, Open-Label Study of Maximally Assisted Therapy (MAT) Compared to Self-Administered Therapy (SAT) for the Treatment of HIV Infection in Antiretroviral Naive Subjects with CD4>200 cells/mm^3

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if there is a difference in HIV viral load levels and CD4 cell (T-cell) counts between patients who have directly observed therapy (maximal assisted therapy) and those who take their medications on their own (self-administered therapy).

About the study:

All patients will take ddI, d4T, nelfinavir and efavirenz (Sustiva). Patients are assigned by chance to be in one of two groups. Those in **Group A** will have an outreach worker visit them for one of their two daily doses on Monday through Friday, to deliver medications and observe patients taking them. Patients in **Group B** will take their medications by themselves and have access to the clinic's regular education and adherence assistance. After six months, all patients will take medications by themselves with no outside observation. Study visits are once a month and the study lasts about one and a half years.

Required:

- CD4 cell (T-cell) range: more than 200
- Viral load range: not applicable
- HIV positive
- At least 13 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of any antiretroviral medications

Location:

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

49. HIV Infection: T-20, Abacavir, Amprenavir, Ritonavir, Efavirenz

Title:

T20-206: A Controlled Phase II Trial Assessing Three Doses of T-20 in Combination With Abacavir, Amprenavir, Ritonavir and Efavirenz in HIV-1 Infected Adults

Type of treatment:

Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Amprenavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
T-20: antiretroviral, fusion inhibitor

Purpose:

To compare three different doses of T-20 when combined with abacavir (Ziagen) or another appropriate NRTI, amprenavir (Agenerase), ritonavir (Norvir) and efavirenz (Sustiva), for safety and effectiveness in lowering the amount of HIV in the blood.

About the study:

All patients will take abacavir or an appropriate NRTI, amprenavir, ritonavir and efavirenz. Patients are assigned by chance to receive one of three doses of T-20 or to receive no T-20 to take in addition to abacavir or NRTI, amprenavir, ritonavir and efavirenz. T-20 is given by injection under the skin twice a day. Patients will know which medications they are taking and at which dose. Study visits are every two weeks for the first month, then once a month. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: more than 400 copies/mL
- HIV positive
- At least 18 years old
- Must have previous use of at least one protease inhibitor for at least 16 weeks prior to study entry

Not allowed:

- Active opportunistic infections
- Prior use of NNRTIs, such as delavirdine, nevirapine or Sustiva
- Women who are pregnant or breastfeeding
- Prior use of abacavir or amprenavir
- Chronic diarrhea (defined as greater than three liquid stools per day which persists for 15 days) within 30 days prior to study entry
- Any cancers, other than basal cell carcinoma of the skin, cervical cancer or KS of the skin or mouth
- Use of any investigational drug within 30 days of study entry
- Prior use of any HIV vaccine

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

ViRx, Inc. - Palm Springs
Vangie Weems
(760) 864-6266

New

50. HIV Infection: Tipranavir, Ritonavir, Fortovase

Title:

M/3342/0016: Tipranavir (PNU-140690): An Open Label, Randomized Study Comparing Combination Therapy (Tipranavir With and Without Ritonavir vs Saquinavir and Ritonavir) Used With Two Nucleoside Reverse Transcriptase Inhibitors in Single Protease Inhibitor-Experienced HIV-1 Patients

Type of treatment:

Fortovase: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor
Tipranavir: antiretroviral, protease inhibitor

Purpose:

To compare two different doses of tipranavir (a new protease inhibitor) when combined with ritonavir; tipranavir alone; or saquinavir plus ritonavir for safety and effectiveness in patients who are failing their first protease inhibitor combination.

About the study:

All patients will take two new NRTIs, such as AZT, ddI, ddC, 3TC, d4T, abacavir or Preveon. In addition, patients are assigned by chance to receive one of two doses of tipranavir combined with ritonavir, **or** tipranavir alone, **or** saquinavir plus ritonavir. All medications are pills and taken by mouth and patients will know which medications they are receiving. After two screening visits, patients will have study visits every two weeks for the first month, then once a month for six months. Patients who have shown an adequate response to the study treatments will be permitted to continue for an additional 24-week extension study.

Required:

- CD4 cell (T-cell) range: more than 50
- Viral load range: more than 5,000 copies/mL
- HIV positive
- At least 13 years old
- At least six months use of current protease inhibitor therapy
- Must be failing present combination containing indinavir, nelfinavir or amprenavir plus two NRTIs
- Must have at least two new NRTI options available

Not allowed:

- Active opportunistic infections
- Prior (more than seven days) use of saquinavir, ritonavir or tipranavir
- Women who are pregnant or breastfeeding
- Use of interferons, interleukins or HIV vaccines within 30 days of study entry
- Active alcohol and/or substance abuse which could interfere with the study

Location:

AIDS Research Alliance
Corie Castro
(310) 358-2429

51. HIV Infection: WF10

Title:

WF10-97-US-004: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Pivotal Clinical Study Evaluating the Safety and Efficacy of WF10 (TCDO) Intravenous Solution in the Management of Patients with Late-Stage HIV Disease

Type of treatment:

WF10 (TCDO): immune modulator

Purpose:

To see if WF10 has any effect on the survival of patients with late-stage HIV disease. To see if WF10 has any effect on disease progression and on the quality of life.

About the study:

Patients are assigned by chance to receive WF10 or placebo (saline). WF10 and placebo are given by infusion into a vein for five consecutive days followed by 16 days of rest (one cycle). Patients will receive four consecutive cycles of treatment. The treatment period lasts eleven weeks. Study visits are at Week 18, then every three months starting at Week 24 and lasting through the first year. Study visits are every six months during the second year. The study lasts for two years.

Required:

- CD4 cell (T-cell) range: 50 or less
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Must have stable (no changes) antiretroviral treatment for at least 30 days prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Current use of interleukins, interferons, G-CSF, GM-CSF, immunoglobulins, cyclosporins or methotrexate
- Any cancers requiring chemotherapy

Location:

UCSF Positive Health Practice
at SFGH/ICTG
Anna Smith, RN
(415) 476-9296 ext. 313

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

52. HIV Infection: d4T, 3TC, Sustiva

Title:

BMS 1445-096: Evaluation of the Safety and Antiviral Activity of Stavudine Extended Release Formulation as Compared to Stavudine Immediate Release Formulation, Each as Part of Potent Antiretroviral Combination Therapy

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To compare a new extended-release d4T to the standard immediate-release d4T when combined with 3TC and Sustiva (efavirenz) for lowering the amount of HIV in the blood.

About the study:

All patients will take 3TC and Sustiva. Patients are assigned by chance to take extended-release d4T once a day plus immediate-release d4T placebo twice a day **or** to take immediate-release d4T twice a day and extended-release d4T placebo once a day. Neither patients nor their doctors will know which they are receiving until the study ends. Study visits are twice a week for the first month, then once a month until Week 16, then every two months. The study lasts at least 48 weeks.

Required:

- CD4 cell (T-cell) range: more than 100
- Viral load range: at least 5,000 copies/mL
- HIV positive
- At least 18 years old

Not allowed:

- Prior use of any antiretroviral medications
- Women who are pregnant or breastfeeding

Location:

AIDS Research Alliance
Corie Castro
(310) 358-2429

East Bay AIDS Center
Lucinda Hopewell, PA-C
(510) 204-4109

New

53. HIV Infection: Treatment Interruption

Title:

H6325-16615-01A: Scheduled Treatment Interruptions to Promote HIV-1 Immunity

Type of treatment:

Observational: none

Purpose:

To see if it is safe to interrupt Highly Active Antiretroviral Theapy (HAART) and to see if an immune response is enhanced with successive periods of treatment interruption.

About the study:

Patients entering the study will remain off antiretroviral therapy for 60 days, then restart their previous HAART treatments for 14 weeks. Patients who again achieve full viral load suppression (<50 copies/mL) will qualify for additional treatment interruption cycles. In addition to blood tests, patients will receive skin tests and thymus CT scans over the course of the study. The study lasts 15 months. When patients are off treatment, they will have study visits once a week. While on treatment, study visits are at Weeks 1, 2, 6, 10, 12, and 14.

Required:

- CD4 cell (T-cell) range: must never have fallen below 100
- Viral load range: currently less than 50 copies/mL **but** must have been greater than 20,000 copies/mL at any time prior to starting the curent HAART treatment
- HIV positive
- Between 18 and 45 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Use of hydroxyurea or immunomodulators (interleukins, interferons) within 12 weeks prior to study entry
- Active alcohol and/or substance abuse which may interfere with the study
- Recent illness within the past 12 weeks that may affect HIV viral load
- Significant medical conditions, including anemia, kidney or liver disease

Location:

Gladstone Institute of Virology and Immunology
Diane Schmidt
(415) 695-3820

New

54. HIV Infection: Treatment Interruption

Title:

H8211-16469-01: An Observational Study Examining the Relationship Between Viral Replication, Viral Fitness With CD4 T Cell Changes in HIV-Infected Patients

Type of treatment:

Observational: none

Purpose:

To study CD4 cell (T-cell) counts and HIV viral load in patients who have stopped taking their antiretroviral medications.

About the study:

Patients will have two baseline visits, then will discontinue their antiretroviral medications for 12 weeks. During these 12 weeks, patients will have study visits once a week, which include an interview, blood tests and a quality of life questionnaire. Weekly study visits will take approximately 30 minutes. The two baseline visits will take 30 - 60 minutes. Patients will receive reimbursement for parking costs.

Required:

- CD4 cell (T-cell) range: less than 300 **before** starting protease inhibitors
- Viral load range: more than 5,000 within the last six months. Currently must be within 10 times the pre-protease inhibitor value
- HIV positive
- At least 18 years old
- Currently taking a protease inhibitor for over 12 months

Not allowed:

- Stopping antiretroviral therapy prior to study entry
- Women who are pregnant or breastfeeding
- Active opportunistic infections
- Active alcohol and/or substance abuse which may interfere with the study
- User of immunosuppressant therapy (such as hydroxyurea, chemotherapy)

Location:

UCSF General Clinical Research Center
Becky Hoh
(415) 476-3669 ext. 1

New

55. HIV Dynamics and Gender and Ovulatory Cycles: Nelfinavir, d4T, 3TC

Title:

The Effect of Gender and Ovulatory Cycle Phase on HIV-1 Dynamics (DYNAMIC STUDY)

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see what differences there are in the time it takes HIV to be reduced in the bloodstream in two groups of women and one group of men who are starting Highly Active Antiretroviral Therapy (HAART)

About the study:

This study will enroll two groups of women and one group of men. Women beginning their menstrual cycle will contact the study coordinator to have a vaginal unltrasound performed. If the ultrasound shows that women are ovulating, they will be assigned by chance to either the early follicular or the midluteal group. A second ultrasound will be done two weeks later to confirm ovulation. If the ultrasound does not suggest ovulation, women will be paid for their participation in the ultrasound but will not join the study. Women in the early follicular group will be admitted to the research clinic for one day after the first vaginal ultrasound while those in the midluteal group will be admitted after the second ultrasound. Men will be admitted at any time. Once admitted, participants will begin taking nelfinavir, d4T and 3TC (HAART) and

then have their HIV RNA viral load levels checked every two hours for six hours (3), then every six hours or 18 hours (3), then once a day for six days. T-cell counts will also be done when patients are admitted and women will have reproductive hormone levels done the same day as the ultrasounds. The study lasts about one month. Women will receive $235 for completing the study and men will receive $205. Men and women can earn an additional $50 if they participate in a substudy to understand differences in the way nelfinavir is processed by the body in men and in women in a different phase of the menstrual cycle. The substudy will last 13 hours, take place on the last day that the viral load testing is done, and will require blood draws every hour for six times, then every two hours for three times.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: more than 10,000 copies/mL
- Women must have regular menstrual cycles
- Between 18 and 45 years old

Not allowed:

- Prior use of any protease inhibitors
- Use of any NRTIs (such as AZT, ddI, ddC, 3TC, d4T or abacavir) within one year of study entry
- Women using hormones (oral or injectable contraceptives)
- Active narcotic or recreational drug use

Location:

Women's Interagency HIV Studies
Sarah Ellison, RN, MSN
(415) 502-8056

New

56. Dyslipidemia and Protease Inhibitors: Abacavir

Title:

ESS 40003: Randomized, Multicenter, Open-Label Trial to Evaluate the Reversibility of Dyslipidemia Upon Substitution of Abacavir for a Protease Inhibitor in Virologically Controlled HIV+ Subjects with Elevated Cholesterol

Type of treatment:

Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if replacing a protease inhibitor with abacavir is effective in lowering the amount of cholesterol in the blood of HIV-infected patients with high cholesterol levels.

About the study:

Patients are assigned by chance to continue taking their protease inhibitor-containing antiretroviral therapy or to replace their protease inhibitor with abavacir. Patients will know to which group they have been assigned. Study visits are once a month and the study lasts 32 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: less than 50 copies/mL
- HIV positive
- At least 18 years old
- Stable (no changes) antiretroviral therapy for at least three months prior to study entry. Therapy must consist of 2 NRTIs plus a protease inhibitor **or** 2 NRTIs plus a protease inhibitor plus ritonavir
- Fasting cholesterol level over 200 mg/dL

Not allowed:

- Past or current AIDS-defining illnesses
- Lipid disorders unrelated to HIV infection
- Women who are pregnant or breastfeeding
- Current treatment for diabetes or for elevated triglycerides/cholesterol
- Prior use of any NNRTI or amprenavir

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

Center for Special Immunology
Sandra Casserella, RN
(714) 751-5800

Institute for HIV Research,
CPMC - Davies Campus
Steve Collinson, RN
(415) 600-6660

57. HIV Infection and Hyperlipidemia: Sustiva

Title:

CCTG 577: Effect of Substituting Efavirenz for Protease Inhibitor Therapy in Patients at Increased Risk for Cardiovascular Complications Due to HIV-Associated Metabolic Disorders

Type of treatment:

Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)

Purpose:

To see if patients who switch from a protease inhibitor to efavirenz (Sustiva) experience greater improvement in lowering the amount of fats in the blood and improving body fat changes.

About the study:

Patients are assigned by chance to switch to efavirenz therapy or to continue protease inhibitor therapy along with two NRTIs. Patients will know to which group they are assigned. Efavirenz is taken once a day at bedtime. All patients will receive diet and exercise counseling. Study visits are once a month for three months, then every three months. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: less than 50 copies/mL
- HIV positive
- At least 18 years old
- Currently taking protease inhibitor and NRTI (two) therapy
- Abnormal fat distribution and/or elevated blood fats

Not allowed:

- Prior use of any NNRTIs, such as delavirdine, nevirapine, MKC-442 or efavirenz
- Women who are pregnant or breastfeeding

Location:

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

58. HIV Infection and Metabolic Changes: HAART

Title:

CPCRA 061: Metabolic Consequences of Highly Active Antiretroviral Therapy (HAART) in HIV-Positive Individuals

Type of treatment:

Observational: none

Purpose:

To compare the three HIV treatment plans used in the FIRST study (CPCRA 058) to determine whether they are the same or different in their effects on blood fats and fat in the waist, hips, and other parts of the body.

About the study:

Patients in this study must also be enrolled in the CPCRA 058 (FIRST) study. Blood draw visits are at Month 1, Month 4, and then every four months. At Baseline and at Months 4, 8, 12, and then every 12 months, patients will be weighed, measured and have a body cell mass test to measure the total amount of fat in the body. Patients will be in this study for at least one year.

Required:

- Coenrollment in the CPCRA 058 (FIRST) study

Not allowed:

- No exclusions

Location:

Castro-Mission Health Center
Mike Jones, RN
(415) 476-9554 ext. 35

Milton Estes, MD
Mike Jones, RN
(415) 476-9554 ext. 35

Robert C. Scott, MD
Paula Pell, RN, MS
(415) 476-9554 ext. 24

San Francisco VA Medical Center
Sherrill Crawford, RN
(415) 476-9554 ext. 14

UCSF Positive Health Practice at Parnassus
Jane Pannell, RN
(415) 476-9554 ext. 23

UCSF Positive Health Practice at SFGH
Jane Pannell, RN
(415) 476-9554 ext. 23

William F. Owen Jr., MD
Sherrill Crawford, RN
(415) 476-9554 ext. 14

59. HIV Infection and T-Cell Production: Observational

Title:

Direct Measurement of Rates of Synthesis and Removal (Turnover) of Lymphocytes and Circulating Human Immunodeficiency Virus (HIV) in Infected Humans

Type of treatment:

Observational: none

Purpose:

To see how quickly new T-cells replace old ones in the blood and lymph tissue and to see how this process is influenced by antiretroviral therapy, infections and other factors.

About the study:

Patients will receive an infusion of glucose (sugar solution) for 12, 24, 48 or 96 hours at the General Clinical Research Center at San Francisco General Hospital. Patients will return to the clinic for up to seven blood draws over the following sixty days. Some patients will have optional tonsil biopsies (a small piece of tonsil tissue is removed) and a bone marrow biopsy (a needle is inserted into the hip bone

and a small piece is removed). **Patients will be paid between $250 and $700 for their participation.**

Required:

- CD4 cell (T-cell) range: more than 100
- Viral load range: varies
- HIV positive
- Must have never taken protease inhibitors before with a detectable viral load **or** have taken protease inhibitor therapy for less than three months with a viral load of less than 500 copies/mL

Not allowed:

- Use of hydroxyurea or any other medication which largely effects T-cell production
- Anemia
- Active infections
- Women who are pregnant or breastfeeding
- Any cancers or other conditions that may effect T-cell production
- Active alcohol and/or substance abuse

Location:

UCSF General Clinical Research Center
Becky Hoh
(415) 476-3669 ext. 1

New

60. Metabolic Changes and Protease Inhibitors: Observational

Title:

H8871-16192-01: Hepatic Insulin Resistance Associated With the Use of Protease Inhibitors

Type of treatment:

Observational: none

Purpose:

To study the metabolic changes associated with antiretroviral medications and increased abdominal fat or "paunch".

About the study:

This study will enroll two groups of patients; those who have never taken a protease inhibitor before and are about to begin, and those who have been taking a protease inhibitor for over a year without abdominal fat gain. During screening, patients will have blood tests, an interview and a body composition analysis which will take half an hour to an hour to perform. The study consists of an overnight visit during which patients will receive non-radioactive nutrients, insulin, glucose (sugar) and somatostatin (used to treat diarrhea). Multiple blood tests will be done during the 24-hour visit. **Patients will be paid $200 for completing the study and their parking lot costs will be covered.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 25 and 50 years old
- Have never taken a protease inhibitor before and are about to begin **or**
- Have been taking a protease inhibitor for over 12 months and have no abdominal fat gain

Not allowed:

- Women who are pregnant or breastfeeding
- Diabetes
- Active opportunistic infections
- Active alcohol and/or substance abuse
- Use of corticosteroids, phenytoin, chemotherapy or beta blockers

Location:

UCSF General Clinical Research Center
Becky Hoh
(415) 476-3669 ext. 1

61. Cerebrospinal Fluid and Potent Antiretroviral Therapy: Observational

Title:

ACTG 736: Cerebrospinal Fluid Human Immunodeficiency Virus-1 (HIV-1) and Cognitive Function in Individuals Receiving Potent Antiretroviral Therapy

Type of treatment:

Observational: none

Purpose:

To see how levels of HIV in the blood compare to those in cerebrospinal fluid (CSF), a fluid found around the brain and spinal cord, before and after the administration of potent antiretroviral therapy.

About the study:

Patients entering this study must also be participating in an ACTG antiretroviral therapy study. Before beginning the antiretroviral therapy study, patients will have blood tests and a lumbar puncture (spinal tap) to see if there is any HIV in the spinal fluid. A spinal tap is the removal of a small amount of fluid from the spinal canal by inserting a needle into the space between the bones in the lower back.

Study visits are at six months, one year and then once a year thereafter. During study visits, patients will have a neurological exam, neuropsychological tests, blood tests and a spinal tap. At the six month visit, patients will need to spend all day at the clinic for multiple blood tests to be taken throughout the day. The length of participation in this study depends on the length of participation in the antiretroviral therapy study.

Required:

- CD4 cell (T-cell) range: less than 200 with a viral load of above 2,000 copies/mL **or**
- A viral load of more than 50,000 copies/mL with any CD4 count
- HIV positive
- At least 18 years old
- Must enroll in this study before starting treatment in an ACTG-sponsored potent antiretroviral therapy study

Not allowed:

- Acute treatment for any infections within four weeks of study entry
- Active alcohol and/or substance abuse which could interfere with the study
- Any active brain infection or cancers
- Pregnant women who require a CT scan

Location:

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

New

62. HIV Infection and the Central Nervous System: Observational

Title:

California Neuro AIDS Tissue Network

Type of treatment:

Observational: none

Purpose:

To observe the effect of HIV and the central nervous system (CNS).

About the study:

Patients will have study visits every six months and detailed medical and neurological testing will be done at each visit. The study will continue for up to five years.

Required:

- CD4 cell (T-cell) range: less than 50 **or** patients who are having neurological problems such as difficulty problem solving and word finding may join with any T-cell count
- Viral load range: not applicable
- HIV positive
- At least 18 years old

Not allowed:

- No exclusions

Location:

Cedars-Sinai Medical Center
Jacqui Pitt, ACRN
(310) 423-3755

UCSD HIV Neurobehavioral Research Center
Sid Wall
(877) 543-8090

University of Southern California CNTN
Ed Lozano, MD
(323) 343-8314

New

63. HIV and Heart Disease: Dietary Intervention

Title:

A Randomized Study Investigating the Effects of Dietary Intervention in Patients with HIV Who are Insulin Resistant

Type of treatment:

Observational: none

Purpose:

To see if certain foods can cause changes in body fat distribution and decrease risk factors for heart disease in HIV-positive individuals.

About the study:

Potential patients will spend two days at the General Clinical Research Center (GCRC) at San Francisco General Hospital to determine if they qualify for the diet intervention. Eligible patients are assigned by chance to one of two diets for two weeks each. Patients will be admitted to the GCRC for two weeks to consume the first diet, discharged for two weeks, then readmitted for two more weeks to consume the second diet. Tests will be conducted at the end of each diet period to determine if the diets deceased risk factors for heart disease.The study lasts six weeks. Patients will be paid for their participation in this study.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Must be on a stable (no changes) medications for at least three months prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Past diabetes, kidney or liver diseases
- Prior use of interferon therapy
- Severe diarrhea
- Current use of carbohydrate or lipid-lowering drugs

Location:

Division of Gastroenterology at SFGH
Jennifer Tuveson
(415) 206-4771

New

64. HIV Infection: Counseling Intervention

Title:

Health-Related Intervention for Persons Living With HIV (Unity Project)

Type of treatment:

Intervention, Natural History:

Purpose:

To explore the usefulness of a program for HIV positive persons. The program addresses issues related to the quality of life, sexuality, and health care among men and women living with HIV.

About the study:

All participants will receive one-on-one counseling and education intervention sessions. Participants are assigned by chance to begin receiving these sessions right away or to wait two years before receiving sessions. Participation will include intervention sessions, regularly scheduled interviews, and blood tests over the course of 30 months. Patients will be compensated for all study activities regardless of when they receive intervention sessions.

Required:

- HIV positive
- At least 18 years old
- Must remain in the San Francisco Bay Area for the next two and a half years

Not allowed:

- No exclusions

Location:

UCSF Center for AIDS Prevention Studies
Neal Carnes
(415) 597-4669

65. HIV Medication Adherence: Alcohol and/or Drug Use

Title:

Challenges in HIV/AIDS Treatment (CHAT)

Type of treatment:

Intervention, Self-Care:

Purpose:

To see if individually tailored problem-solving sessions can help improve HIV medication adherence and lower the amount of HIV in the blood of HIV-positive patients who use alcohol or drugs.

About the study:

Patients are assigned by chance to receive six problem-solving sessions or to receive their usual care. All patients will have interviews every four months for one year. All patients will also have T-cell counts and HIV viral load tests done every four months. **Patients will be paid $30 for the first interview with $5 increments at each following interview every three months for one year ($30, $35, $40, $45, $50).**

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 50 copies/mL
- HIV positive
- At least 18 years old
- Must be taking antiretoviral medications
- At least 3 drinks at a sitting during the last seven days and/or use of any recreational drugs in the past 30 days
- Enrollment limited to residents of San Francisco

Not allowed:

- No exclusions

Location:

UCSF Center for AIDS Prevention Studies
Andre Maiorana
(415) 597-9204

New

66. HIV Medication Adherence: Medication Manager, Electronic Reminder System

Title:

CPCRA 062: Adherence Strategies Using a Medication Manager and an Electronic Medication Reminder System for HIV-Infected Patients Receiving HAART

Type of treatment:

Observational: none

Purpose:

To look at different ways to help patients follow their anti-HIV medication schedule. Taking these drugs correctly may help the drugs work better to lower the amount of HIV in the blood for a longer time.

About the study:

Patients enrolling in this study must also be enrolled in the CPCRA FIRST (058) or PIP (057) studies. Patients will be assigned by chance to one of four adherence groups. **Group 1** will use the Medication Manager Plan. Patients in this group will work closely with a member of the research staff to help them understand the importance of taking their medications as directed and how to take them correctly. Patients in **Group 2** will use the Electronic Medication Reminder System Plan. Patients in this group will carry a small device (ALR - A Little Reminder) that will beep and flash when it is time to take antiretroviral medications. **Group 3** patients will use both the Medication Manager and the Electronic Medication Reminder System. Patients in **Group 4** will use the medication adherence system already being used at their research site rather than use the Medication Manager or the Electronic Medication Reminder System. Patients will be in this study for as long as they are being followed in the FIRST or PIP studies.

Required:

- Enrollment into the FIRST or PIP (058 or 057) CPCRA studies

Not allowed:

- No exclusions

Location:

Castro-Mission Health Center
Mike Jones, RN
(415) 476-9554 ext. 35

Milton Estes, MD
Mike Jones, RN
(415) 476-9554 ext. 35

Robert C. Scott, MD
Paula Pell, RN, MS
(415) 476-9554 ext. 24

San Francisco VA Medical Center
Sherrill Crawford, RN
(415) 476-9554 ext. 14

UCSF Positive Health Practice at Parnassus
Jane Pannell, RN
(415) 476-9554 ext. 23

UCSF Positive Health Practice at SFGH
Jane Pannell, RN
(415) 476-9554 ext. 23

William F. Owen Jr., MD
Sherrill Crawford, RN
(415) 476-9554 ext. 14

67. HIV-Associated Anemia: Procrit

Title:

PR98-29-002: The Effect of Weekly Dosing Regimen of Procrit on the Quality of Life in the Treatment of Anemia in HIV-Infected Patients on Antiretroviral Therapy

Type of treatment:

Erythropoietin: red blood cell stimulator

Purpose:

To see if Procrit (erythropoietin) is effective in treating anemia and improving the quality of life in HIV-infected patients who are taking antiretroviral theapy.

About the study:

All patients will receive Procrit once a week. Procrit is given by injection under the skin. If a patient's hemoglobin does not increase by one gram/dL after four weeks, the dose of Procrit will be increased. Patients will receive Procrit for a maximum of 16 weeks. Patients will also take an iron supplement throughout the study. The study lasts 16 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 75 years old
- Hemoglobin of less than 11 grams/dL
- Blood erythropoietin level of less than 500 mU/mL
- On stable (no changes) antiretroviral therapy for at least four weeks prior to study entry

Not allowed:

- Active opportunistic infections or AIDS-defining illness
- Past or current uncontrolled high blood pressure (diastolic blood pressure >100 mmHg)
- Anemia caused by iron deficiency, hemolysis or gastrointestinal bleeding
- Women who are pregnant or breastfeeding
- Active alcohol and/or substance abuse
- Current treatment with ganciclovir and/or interferons

Location:

AltaMed HIV Services
Monica Lopez
(323) 869-5429

St. Luke Medical Group & Clinical Trials
Ida Proctor
(619) 235-0501

68. HIV-Associated Anemia: Procrit

Title:

PR99-29-001: A Randomized Study to Compare the Safety and Efficacy of Procrit (Epoetin alfa) Once a Week versus Standard of Care for the Treatment of Anemia in HIV-Infected Individuals Receiving Medical Care at an HMO

Type of treatment:

Erythropoietin: red blood cell stimulator

Purpose:

To see if Procrit (also called erythropoietin) can improve anemia caused by HIV or HIV medications.

About the study:

Patients are assigned by chance to receive Procrit or to receive the standard treatment for anemia by their doctor. Procrit is given by injection under the skin once a week. Patients assigned to receive Procrit will have clinic visits once a week for injections and those assigned to standard care will have study visits at Weeks 2, 8, 12 and 16. The study lasts 16 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Hemoglobin between 9 and 11 grams/dL
- Serum erythropoietin level 500 or less mU/mL

Not allowed:

- Active opportunistic infections or AIDS-defining illnesses
- Diastolic blood pressure over 100 mmHg
- Anemia caused by factors other than HIV, such as iron, B12 or folate deficiency, or gastrointestinal bleeding
- Women who are pregnant or breastfeeding
- Active alcohol and/or substance abuse
- Use of Procrit (erythropoietin) within six months of study entry

Location:

Kaiser Permanente Clinical Trials Unit, San Francisco
Anna Dowling, RN
(415) 202-3487

69. Aspergillosis Treatment: FK463

Title:

98-0-046: An Open-Label, Non-Comparative Study of FK463 for the Treatment of Invasive Aspergillosis

Type of treatment:

FK463: antifungal

Purpose:

To see if FK463 is safe and effective for patients with proven or probable invasive infections due to *Aspergillus*.

About the study:

All patients will receive FK463 once a day as a one hour infusion into a vein. Patients will receive FK463 for at least seven consecutive days and up to a maximum of 90 days, depending on the patient's clinical response. The dose of FK463 can be increased during the study depending on the clinical response of the patient. Study visits are once a week and at six weeks following the last dose of FK463. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Diagnosis of *Aspergillus*, either newly diagnosed, inadequate response from standard antifungal therapy, or those who could not tolerate standard antifungal therapy

Not allowed:

- Newly diagnosed patients with more than 48 hours use of systemic antifungal therapy

Location:

Institute for HIV Research, CPMC - Davies Campus
Steve Collinson, RN
(415) 600-6660

70. Oral Candidiasis Prevention: Self-Care Intervention

Title:

Self-Care Intervention to Prevent Oral Candidiasis

Type of treatment:

Intervention, Self-Care:

Purpose:

To see if a program of dietary and oral hygiene instruction (PRO-SELF:CANDIDIASIS) is effective in increasing the time between episodes of oral candidiasis (thrush) in HIV-infected patients. To see if patients in the PRO-SELF:CANDIDIASIS program report a recurrence of oral thrush more accurately than HIV-infected patients not using the program.

About the study:

Patients are assigned by chance to participate in the PRO-SELF:CANDIDIASIS program of diet modification and intensive oral hygiene or not to be in this program. Study

visits will be every two weeks and the study lasts six months. Nystatin vaginal tablets or a prescription for the patient's antifungal drug of choice (mycelex or fluconazole) will be provided to treat episodes of oral candidiasis that occur during the study. As part of the study, all patients will have their teeth professionally cleaned twice, once at the beginning and at the end of the study. Patients will be paid $155 for completing this study.

Required:

- HIV positive
- At least 18 years old
- Must have had at least one episode of oral candidiasis in the past

Not allowed:

- Continuous use of oral or systemic antifungal medications

Location:

UCSF Stomatology Clinical Center
Laurie MacPhail, DMD
(415) 476-1690

71. Candidemia or Invasive Candidiasis Treatment: FK463

Title:

98-0-047: An Open-Label, Non-Comparative Study of FK463 in the Treatment of Candidemia or Invasive Candidiasis

Type of treatment:

FK463: antifungal

Purpose:

To see if FK463 is safe and effective in patients with confirmed Candida in the blood or candidiasis that has spread to the internal organs.

About the study:

All patients will receive FK463 once a day as a one hour infusion into a vein. Patients will receive FK463 for at least five consecutive days and up to a maximum of six weeks, depending on patient's clinical response. The dose of FK463 may be increased throughout the study depending on the clinical response of the patient. Study visits are once a week while on treatment and a visit six weeks following the last dose of FK463. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Newly diagnosed with candidemia or invasive candidiasis or for patients who have received more than five days on antifungal therapy with no response

Not allowed:

- Newly diagnosed patients with more than 48 hours use of systemic antifungal therapy

Location:

Institute for HIV Research,
CPMC - Davies Campus
Steve Collinson, RN
(415) 600-6660

72. Oropharyngeal Candidiasis Treatment: Fluconazole

Title:

ACTG 323/MSG 40: A Phase III Randomized Study of the Use of Fluconazole as Chronic Suppressive Therapy Versus Episodic Therapy in HIV Positive Subjects With Reccurent Oropharyngeal Candidiasis

Type of treatment:

Fluconazole: antifungal

Purpose:

To find out if it is better to take fluconazole three times a week to prevent thrush or esophageal candidiasis from coming back, or to wait until thrush or esophageal candidiasis reappears before taking it.

About the study:

Patients are assigned by chance to take fluconazole three times a week, or to take fluconazole only if they get thrush or esophageal candidiasis. There are no placebos in this study. Patients who join the study when they have thrush or esophageal candidiasis will be treated with fluconazole first, and then assigned by chance to take fluconazole every week, or to wait until they get thrush or esophageal candidiasis again. Study visits are every two months. Blood samples are drawn at each study visit. The study lasts two years.

Required:

- CD4 cell (T-cell) range: 150 or less
- HIV positive
- At least 13 years old
- At least one episode of oropharyngeal candidiasis (thrush) within the past six months

Not allowed:

- Three or more episodes of oropharyngeal candidiasis within the past three months
- Prior esophageal candidiasis
- Women who are pregnant or breastfeeding
- Any fungal infection requiring treatment with amphotericin-B, terbinafine, Lamisil or Ancoban
- Acute or active opportunistic infection requiring treatment

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

73. CMV Retinitis Treatment: Cidofovir, Ganciclovir

Title:

ACTG 350/GCCRT: The Ganciclovir and Cidofovir CMV Retinitis Trial (GCCRT)

Type of treatment:

Cidofovir: antiviral
Ganciclovir, eye implants: antiviral
Ganciclovir, oral: antiviral

Purpose:

To compare the use of cidofovir to the use of ganciclovir implants plus oral ganciclovir with respect to the effectiveness in preventing vision loss in patients with CMV retinitis.

About the study:

Patients are assigned by chance to receive intravenous cidofovir or to receive ganciclovir intraocular implants and oral ganciclovir. Patients will know which treatment they are receiving. Patients assigned to receive cidofovir will have cidofovir given intravenously once a week for the first two weeks, then once every two weeks thereafter. Patients assigned to ganciclovir will have an intraocular device surgically implanted at baseline and every six to eight months thereafter in eyes with CMV retinitis. Oral ganciclovir is a pill and patients take four pills three times a day. Study visits are every four weeks. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Active CMV retinitis
- Visual acuity of 20/100 or better in at least one eye
- At least one lesion 750 microns or greater in size that can be photographed

Not allowed:

- Previous CMV treatment with cidofovir or the ganciclovir intraocular device
- Allergy to probenecid or sulfa sepsis syndrome
- Clinically significant cardiac disease, ischemia, congestive heart failure or arrhythmia
- Women who are pregnant or breastfeeding
- Current alcohol or substance abuse

Location:

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

UCLA - Jules Stein Eye Institute
Michael Cornish, Ph.D.
(310) 794-5608

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

University of Southern California ACTU
Jennifer Lim, MD
(323) 342-6467

74. CMV Retinitis: Safety Study

Title:

ACTG 379: Discontinuation of Maintenance Therapy for Cytomegalovirus (CMV) Retinitis After Immune Reconstitution by Potent Antiretroviral Therapy: Safety, Virology and Immunology Profiles

Type of treatment:

Observational: none

Purpose:

To see if it is safe to discontinue CMV retinitis maintenance therapy for patients whose retinitis has healed and are taking HAART (Highly Active Antiretroviral Therapy)

About the study:

There are three groups of patients in this study. Patients in **Groups 1 and 2** (see required below) will discontinue taking CMV retinitis maintenance treatment at the beginning of the study. Patients in **Group 3** are those that do **not** wish to stop taking their CMV retinitis maintenance treatment. If patients' CMV reactivates or if their T-cell count falls below 50 cells/mm^3, CMV medications may be restarted. After screening, study visits are every two weeks for the first two months,

then once a month until the end of the study. Some study visits will include blood tests and eye exams (with photographs). Patients whose T-cell counts fall below 50 cells/mm^3 will have eye exams every two weeks. Patients whose CMV retinitis comes back will have their CMV medications restarted and be asked to return to the clinic for an additional eight months. The study lasts at least one year.

Required:

- CD4 cell (T-cell) range:
  Group 1: more than 100
  Group 2: between 50 amd 100 **and** a 2 or more log_{10} reduction in viral load or undetectable viral load in response to HAART
  Group 3: at least 50
- Viral load range: Groups 1 and 3: not applicable
- HIV positive
- At least 13 years old
- Healed CMV retinitis after receiving treatment with any anti-CMV therapies for at least eight months prior to study entry; patients with ganciclovir implants must have had the implant for at least seven months prior to study entry
- At least eight weeks of HAART (any combination of at least two of the following: protease inhibitors, NRTIs, or NNRTIs)

Not allowed:

- Ganciclovir intraocular implants for less than seven months
- Any retinal lesions which would interfere with the ability to detect CMV retinitis reactivation or progression
- Any cancers requiring chemo or radiation therapy
- Evidence of any CMV disease outside of the eye which requires the use of anti-CMV medications

Location:

Stanford University Medical Center
Debbie Slamowitz, RN
(650) 723-2804

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

University of Southern California ACTU
Gil Clemente, RN
(323) 343-8284

75. HIV and Ocular Complications of AIDS: Observational

Title:

LSOCA: Longitudinal Study of the Ocular Complications of AIDS

Type of treatment:

Observational: none

Purpose:

To see the effect of Highly Active Antiretroviral Therapy (HAART)-induced changes in the immune system on the risk of CMV retinitis and other ocular complications of AIDS. To determine the characteristics of populations at high risk for CMV retinitis and other ocular complications of AIDS.

About the study:

Both patients with and without ocular complications will be enrolled in this study. At baseline, all participants will have complete ophthalmologic exams with photographs of the eye, blood tests, medical history interview and a quality of life questionnaire. Those participants who have ocular complications will have clinic visits every three months, including ophthalmologic exams with photographs and blood tests. Those participants who do not have ocular complications will have a clinic visit every six months and a telephone call every three months. At clinic visits, these patients will have blood tests and ophthalmologic exams but no ocular photography. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive with an AIDS diagnosis (CDC-defined)
- At least 13 years old

Not allowed:

- No exclusions

Location:

UC Irvine Department of Ophthalmology
Karen Lopez, BS, COA
(949) 824-8303

UCLA - Jules Stein Eye Institute
Michael Cornish, Ph.D.
(310) 794-5608

76. AIDS Dementia Complex Treatment: Memantine

Title:

ACTG 301: A Phase II, Randomized, Double-Blind, Placebo-Controlled Trial of Memantine for AIDS Dementia Complex (ADC) Alone or As Concurrent Treatment with Antiretroviral Therapy

Type of treatment:

Memantine: antiviral

Purpose:

To see if memantine has any effect on improving AIDS Dementia Complex. To see if memantine may have any effect on relieving painful peripheral neuropathy in patients being treated with antiretroviral therapy.

About the study:

There are two parts to this study. In Part A, patients will be assigned by chance to receive memantine or placebo. This part of the study is dose-ranging, which means that patients assigned to receive memantine will take the lowest dose for the first week. The dose will be increased weekly to a maximum dose of 40mg per day during the fourth week. Neither patients nor their doctors will know whether they are taking memantine or placebo for the first 20 weeks. After 16 weeks, patients will stop taking memantine or placebo for four weeks. In Part B, after those four weeks of no study medication, all patients will be offered open-label (real) memantine to take for 60 weeks (an initial 12-weeks plus an additional 48-week extension). Study visits are once a week for the first month, then once a month until Week 20. During the initial open-label phase, memantine will again be given in weekly dose increases for four weeks and study visits are again once a week for the first four weeks.There are four lumbar punctures (spinal taps) required; one at screening, the second at Week 16 of Part A, and again at Weeks 16 and 48 of Part B. A spinal tap is a procedure whereby a small amount of fluid is removed from the spinal canal by inserting a needle into the space between the bones in the lower back.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of AIDS Dementia Complex (ADC), stage 1, 2, or 3
- Patients who are taking antiretoviral medications must be on stable treatment for at least six consecutive weeks prior to study entry and maintain this treatment throughout the study
- Impaired cognitive function as evidenced by neuropsychological tests

Not allowed:

- Any cancers other then basal cell, cervical or KS of the skin
- Any psychiatric diagnosis, such as schizophrenia or severe bipolar illness, which may affect the analysis of the study
- Active AIDS-defining opportunistic infections
- Neurologic disease unrelated to HIV, such as multiple sclerosis, stroke, degenerative disease
- Seizure disorder
- CNS infections or neoplasms, such as toxoplasmosis, CNS lymphoma, PML, cryptococcal meningitis, untreated syphilis
- Women who are pregnant or breastfeeding
- Active alcohol or drug abuse which may interfere with the study

Location:

UCSF Positive Health Practice at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

77. HIV and Hepatitis C Infection: Observational

Title:

ACTG 383: Dynamics of Hepatitis C Infection in Subjects with Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) Receiving Highly Active Antiretroviral Therapy (HAART)

Type of treatment:

Observational: none

Purpose:

To learn more about hepatitis C virus (HCV) in patients who are taking Highly Active Antiretroviral Therapy (HAART). To see if patients co-infected with hepatitis C have more frequent liver function test abnormalities while receiving HAART.

About the study:

Patients enrolled in this study must also be co-enrolled in another ACTG-sponsored research study which uses Highly Active Antiretroviral Therapy to treat HIV. No study treatments are given as part of this study. This study only involves the evaluation of blood tests for hepatitis C virus. Blood draws are at weeks 2, 4, 8, 16, 24, 32, 40 and 48. The study lasts 48 weeks.

Required:

- Viral load range: at least 2,500 copies/mL
- At least 13 years old
- Have tested positive for hepatitis C virus
- Must be co-enrolled in another ACTG primary trial using HAART within 72 hours of entry into this study

Not allowed:

- More than two weeks use of any protease inhibitors
- Prior use of hydroxyurea, Sustiva, abacavir, adefovir dipivoxil
- Liver disease, manifested by ascites, bleeding varices, coagulation disorders
- Active hepatitis B infection
- Use of interferon for any reason within three months of study entry
- Active alcohol and/or substance abuse
- Use of immunomodulators, such as interleukins, DNCB, thalidomide, thymopentin within four weeks of study entry
- Any cancers requiring systemic chemotherapy

Location:

Harbor-UCLA Medical Center
Mario Guerrero, MD
(310) 222-3848

Marin County Specialty Clinic
Joann Volinski, RN
(415) 499-7377

Stanford University Medical Center
Jane Norris, PA-C
(650) 723-2805

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

78. HIV and Hepatitis C Treatment: Alpha Interferon

Title:

IFN 9701: Evaluation of the Safety and Efficacy of Alferon N Injection in the Treatment of Subjects Co-Infected with HIV and Hepatitis C

Type of treatment:

Interferon, alpha: immune modulator

Purpose:

To see if Alferon N (interferon alpha-n3) is safe and effective in treating patients who are infected with chronic hepatitis C and co-infected with HIV.

About the study:

All patients will receive Alferon N injections. There are no placebos in this study. Alferon N is given by injection into a muscle three times a week. Patients who have not had a liver biopsy within 12 months of study entry will be required to undergo one prior to being screened for this study. Study visits are every two weeks for the first month, then once a month. The study lasts six months.

Required:

- CD4 cell (T-cell) range: at least 200
- HIV viral load range: not applicable
- Hepatitis C viral load range: at least 2,000 copies/mL
- Between 18 and 60 years old
- HIV positive
- Biopsy-proven hepatitis C

Not allowed:

- Prior hepatitis B
- Prior occurence of liver failure
- Prior use of alpha interferon

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-7377

New

79. HIV and Hepatitis C Treatment: Pegylated Interferon, Alpha Interferon, Ribavirin

Title:

NR15961: A Randomized, Partially-Blinded, Multicenter, Phase III, Three-Arm Study Evaluating the Efficacy and Safety of Peginterferon alfa-2a (Ro25-8310) Monotherapy versus Combination Therapy of Peginterferon alfa-2a with Ribavirin (Ro 20-9963) versus Combination Therapy of Interferon alfa-2a (Ro 22-8181) with Ribavirin for 48 Weeks and 24 Weeks of Follow-up in Patients with Chronic Hepatitis C Coinfected with Human Immunodeficiency Virus

Type of treatment:

Interferon, Pegylated: immune modulator
Interferon, alpha: immune modulator
Ribavirin: antiviral

Purpose:

To compare pegylated interferon (a long-acting form of interferon) alone to pegylated interferon plus ribavirin and to alpha interferon plus ribavirin on the amount of hepatitis C virus in the blood.

About the study:

Patients are assigned by chance to one of three groups. The first group will take pegylated interferon (PEG Intron) plus ribavirin placebo. The second group will take PEG Intron plus ribavirin. The third group will take alpha interferon plus ribavirin. PEG Intron is given by injection under the skin once a week. Alpha interferon is given by injection under the skin three times a week. Ribavirin and its placebo are pills and taken by mouth. Patients assigned to take PEG Intron will not know if

they are taking ribavirin or placebo until the study is over. Treatment lasts 48 weeks and study visits are every two weeks for the first two months, then at Week 12, and then every six weeks. Patients will have three study visits after treatment has ended. (Weeks 52, 60, 72).

Required:

- CD4 cell range: at least 200 with any HIV viral load **or**
- Between 100 and 199 with a viral load of less than 5,000 copies/mL
- HIV positive
- At least 18 years old
- Detectable hepatitis C virus (more than 1,000 copies/mL)
- Patients on Highly Active Antiretroviral Therapy (HAART) must be on stable (no changes) therapy **or** patients who have not been on HAART for at least eight weeks prior to study entry must be willing to delay starting HAART for at least six weeks

Not allowed:

- Women who are pregnant or breastfeeding
- Male partners of women who are pregnant
- Prior use of interferon or ribavirin
- Active opportunistic infections or malignancies requiring systemic therapy
- Use of any investigational drugs within six weeks of study entry
- Past or current evidence of any chronic liver diseases other than hepatits C
- Severe seizure disorder
- Active alcohol and/or substance abuse which may interfere with the study
- Significant cardiac, pulmonary or thyroid diseases
- Use of any chemotherapy or immunomodulators (interleukins, interferons) within six months of study entry

Location:

Quest Clinical Research, San Francisco
Jacob Lalezari, MD
(415) 353-0800

80. HIV and Hepatitis C-Associated Anemia: Procrit

Title:

An Open-Label, Single-Arm Study Evaluating Procrit Treatment for Anemia Associated with Patients Co-Infected with HIV and HCV Receiving Ribavirin and IFN-alfa-2b Treatment

Type of treatment:

Erythropoietin: red blood cell stimulator

Purpose:

To see if Procrit (EPO, erythropoeitin) is effective in improving the quality of life and alleviating anemia in patients with HIV and hepatitis C who are taking ribavirin and alpha interferon.

About the study:

Patients who are coinfected with HIV and hepatitis C and are starting ribavirin and alpha interferon (or patients who have had less than nine months treatment with ribavirin and interferon) are eligible to participate in this study. Patients will be observed for signs of anemia and have study visits on Day 1, Weeks 2 and 4, then every four weeks for 12 months. If patients' hemoglobin falls below 12.0 g/dL, they will receive Procrit by injection under the skin once a week until the hemoglobin exceeds 14.0 g/dL for women and 16.0 g/dL for men. HIV and hepatitis C viral load levels will also be tested. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Evidence of hepatitis C by viral load, liver enzymes and liver biopsy (if available)
- At least 18 years old
- Stable (no changes) antiretroviral therapy for at least four weeks prior to study entry

Not allowed:

- Liver disease due to other causes (such as alcohol, hepatitis B or autoimmune diseae)
- History of ascites, bleeding varices or encephalopathy
- Active acute opportunistic infections
- Use of Procrit in the past three months

Location:

HIVCare,
Saint Francis Memorial Hospital
Mark Bowers
(415) 353-6215

81. Genital Herpes Suppression: Valacyclovir

Title:

H5230018: An International, Randomized, Double-Blind, Placebo-Controlled Study of Valacyclovir for the Suppression of Recurrent Ano-Genital HSV Infections in HIV-Infected Subjects

Type of treatment:

Valacyclovir: antiviral

Purpose:

So see if valacyclovir (Valtrex) is safe and effective in preventing outbreaks of genital herpes in people infected with the HIV virus.

About the study:

Patients are assigned by chance to receive valacyclovir (Valtrex) or to receive placebo. Neither patients nor their doctors will know which they are taking until the study ends. Valacyclovir and its placebo are pills and taken by mouth twice as day. Any patients who develop an outbreak of genital herpes will be treated with open label (real) valacyclovir for six months, then resume suppressive therapy with open label valacyclovir. Study visits are once a month and the study lasts for six months. **Patients will be reimbursed $20 for each visit they attend.**

Required:

- CD4 cell (T-cell) range: more than 100
- HIV positive
- At least 18 years old
- On stable (no changes) antiretroviral therapy for at least six months prior to study entry
- A history of four or more genital herpes outbreaks per year

Not allowed:

- Women who are pregnant or breastfeeding
- Known allergy to acyclovir, valacyclovir, famciclovir or ganciclovir
- Malabsorption, vomiting or gastrointestinal dysfunction
- Lactose intolerant
- Current use of any anti-herpes medications or current use of interferons

Location:

East Bay AIDS Center
Lucinda Hopewell, PA-C
(510) 204-4109

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

82. Histoplasmosis Treatment: Observational

Title:

ACTG A5038: Discontinuation of Antifungal Therapy for Histoplasmosis Following Immunologic Response to Antiretroviral Therapy

Type of treatment:

Observational: none

Purpose:

To see if histoplasmosis preventive medications can be stopped in patients who have had histoplasmosis before, been treated for at least 12 months and are now free of any signs of histoplasmosis and have CD4 (T-cell) counts of 150 cells/mm^3 or more.

About the study:

On the day of study entry, patients will have blood tests and skin tests done and stop histoplasmosis treatment (itraconazole). Study visits are once a month for the first two months, then every two months. If patients redevelop histoplasmosis, they will resume treatment with itraconazole and be followed in the study. If patients CD4 (T-cell) counts are repeatedly found to be 100 cells/mm^3 or less, they will be asked to restart histoplasmosis treatment and will continue with the study. The study may last for about two years

Required:

- CD4 cell (T-cell) range: two counts of more than 150, one within six months and one within 30 days of study entry
- HIV positive
- At least 13 years old
- Previous documented case of histoplasmosis
- Antiretroviral treatment for at least 24 weeks and stable (no changes) therapy for at least eight weeks prior to study entry
- Histoplasmosis remission after at least 12 consecutive months of itraconazole

Not allowed:

- Women who are pregnant or breastfeeding
- Presence of clinical or laboratory findings consistent with relapse of histoplasmosis within four weeks of study entry
- Use of immunomodulators (such as interleukins or interferons), chemotherapy or corticosteroids within the last two months. Hydroxyurea use is allowed
- Meningitis or lesions of the brain or spinal cord thought to be caused by *H. capsulatum* infection
- Active systemic infections

Location:

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

83. Herpes Simplex: Observational

Title:

Multisite Antiviral Resistance Studies; Pilot Surveillance for Acyclovir-Resistant HSVII

Type of treatment:

Observational: none

Purpose:

To determine the extent of acyclovir-resistant herpes simplex. To collect and store specimens of acyclovir-resistant genital herpes simplex for in-depth lab studies.

About the study:

Patients joining this study will have one study visit where a herpes swab will be taken and patients will fill out a questionnaire. **Patients will be paid $20 for completing this study.**

Required:

- HIV positive
- At least 18 years old
- Herpes simplex lesion in the genital, anal, oral or facial region

Not allowed:

- No exclusions

Location:

UCSF Positive Health Practice
at SFGH/ICTG
Jessica Silversmith
(415) 476-9296 ext. 322

New

84. Herpes Zoster Treatment: Valacyclovir

Title:

A Double-Blind Study Comparing Two Doses of Valacyclovir HCl for the Treatment of Uncomplicated Herpes Zoster in Immunocompromised Patients 18 Years of Age or Older

Type of treatment:

Valacyclovir: antiviral

Purpose:

To see if valacyclovir is safe and effective in treating acute herpes zoster (shingles) in HIV-positive persons.

About the study:

Patients are assigned by chance to receive one of two doses of valacyclovir HCl. Neither patients nor their doctors will know which dose they are receiving until the study ends. All patients will receive valacyclovir, there are no placebos in this study. Study visits are twice a week for the first two weeks, then every two weeks for the first month, then once a month. The study lasts six months

Required:

- CD4 cell (T-cell) range: more than 50
- HIV positive and/or other immune dysfuction, any cancer, organ/bone transplant patients
- At least 18 years old
- Must have a diagnosis of uncomplicated herpes zoster and come into the clinic within 72 hours of the appearance of the rash

Not allowed:

- Women who are pregnant or breastfeeding
- Disseminated herpes zoster
- Use of any anti-zoster medications within four weeks of study entry
- Current use of probenecid
- Organ or bone transplants within nine months of study entry

Location:

Kraus Medical Partners
Mike Heinzel
(323) 930-2324

85. AIDS-Related Cancers: Observational

Title:

Cohort and Nested Case-Control Study of AIDS-Related Non-Hodgkin's Lymphoma, Kaposi's Sarcoma and Other Malignancies

Type of treatment:

Observational: none

Purpose:

To collect data and specimens on cancers occuring in HIV-infected patients for studies of the causes of these cancers.

About the study:

Medical data will be collected every six months from clinic visits and interviews and/or questionnaires. Patients will have blood drawn once a year to test for cancers and possible relevant HIV/AIDS tests. If patients have surgery or a biopsy for their cancer, and there is enough tissue, it may be sent to the National Cancer Institute for HIV tests. The study lasts three years.

Required:

- CD4 cell (T-cell) range: 200 or less
- HIV positive
- At least 18 years old
- AIDS-related cancer, such as KS or non-Hodgkin's lymphoma

Not allowed:

- No exclusions

Location:

Pacific Oaks Research Group
Gary Aquino, LVN
(310) 360-8800

86. KS Treatment: IM862

Title:

AMC013: A Phase III, Randomized, Placebo-Controlled and Double-Blind Study of IM862 for Patients With Mucocutaneous AIDS-Associated Kaposi's Sarcoma

Type of treatment:

IM862: immune modulator, antitumor

Purpose:

To compare complete and partial responses to KS lesions between IM862 and placebo. To see if IM862 has any effect on HIV.

About the study:

Patients are assigned by chance to receive IM862 or placebo. Both IM862 and its placebo are given as a nasal solution, like taking nose drops. Patients will be instructed how to give themselves the nasal solution on the first day. Patients will use the study drug every other day. Patients will receive treatment as long as their KS remains

stable or improves. Patients may be asked to undergo a biopsy during the study. Study visits are once a month and the study will lasts six months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven KS with five or more lesions involving the skin or the oral cavity
- Patients on antiretroviral therapy must be on stable (no changes) treatment for at least eight weeks prior to study entry

Not allowed:

- KS of the internal organs
- Women who are pregnant or breastfeeding
- Active opportunistic infections other than genital herpes within two weeks of study entry
- Acute and severe upper respiratory congestion due to concerns regarding absorption of medication being given through the nose
- Use of interferons, interleukins, chemotherapy, thalidomide or glucocorticoids within four weeks of study entry
- Radiation treatment to any study lesion within four weeks of study entry
- Prior use of IM862
- Past or current cancers other than KS except, basal cell carcinoma of the skin or cervical cancer
- Active alcohol and/or substance abuse

Location:

AIDS Oncology Practice at
UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

LAC-USC Medical Center
Norris Cancer Hospital
Suzanne Cabriales, RN
(323) 343-8270

Marcus Conant, MD Clinical Research
Chris Eden, MD
(415) 759-4126

UCSF Positive Health Practice
at SFGH/ICTG
Ron Frianeza
(415) 476-9296 ext. 316

University of Southern California AMC
Suzanne Cabriales, RN
(323) 343-8270

87. KS Treatment: Paclitaxel, DOXIL

Title:

AMC009: Phase III Trial of Paclitaxel Versus Liposomal Doxorubicin for the Treatment of Advanced AIDS-Associated Kaposi's Sarcoma

Type of treatment:

Doxil: chemotherapy
Paclitaxel: chemotherapy

Purpose:

To compare paclitaxel and liposomal doxorubicin (DOXIL) for safety, tolerability and response rate to advanced KS lesions. To see if each of these two treatments has any effect on the HIV virus.

About the study:

Patients are assigned by chance to receive paclitaxel (Taxol) or liposomal doxorubicin, also called DOXIL. Patients will know which treatment they are receiving. Paclitaxel is given by infusion into a vein over a three-hour period every two weeks. DOXIL is given as an infusion into a vein over a 30-60 minute period every two weeks. Patients will receive treatment for as long as their KS is improving or for at least two treatments after their KS has gone away. Study visits are every two weeks and patients will be asked to complete a questionnaire about the quality of their life. The study lasts at least two years.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven measurable KS with any of the following:
  -KS of the internal organs,
  -tumor-related lymphedema,
  -tumor-related ulcers or pain,
  -oropharyngeal or involvement of the eye
- Must be on stable combination antiretroviral therapy for at least 14 days prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Prior systemic chemotherapy for KS
- Radiation therapy within seven days prior to study entry or any radiation to study lesions
- Active, untreated infections
- Past or current other cancers, except basal cell carcinoma of the skin or cervical cancer

Location:

AIDS Oncology Practice at
UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

LAC-USC Medical Center
Norris Cancer Hospital
Suzanne Cabriales, RN
(323) 343-8270

UCSF Positive Health Practice
at SFGH/ICTG
Ron Frianeza
(415) 476-9296 ext. 316

University of Southern California AMC
Suzanne Cabriales, RN
(323) 343-8270

88. KS Treatment: Paclitaxel, Protease Inhibitors

Title:

AMC014: Pilot Study to Evaluate the Potential Interactions Between Paclitaxel and Protease Inhibitors in Patients with AIDS-Related Kaposi's Sarcoma

Type of treatment:

Paclitaxel: chemotherapy

Purpose:

To see if paclitaxel is safe and effective in treating KS and to see how in interacts with protease inhibitors.

About the study:

All patients will receive paclitaxel (also called Taxol) by infusion into a vein. Infusions take about three hours and are given every two weeks (a cycle). Patients will continue to receive paclitaxel as long as their KS is stable or improving. Patients will be allowed two treatments of paclitaxel after a complete remission of their KS. Patients whose KS gets worse will be discontinued from the study. Blood tests will be performed once a week.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven, measurable, symptomatic KS

Not allowed:

- Women who are pregnant or breastfeeding
- Systemic KS treatment within two weeks of study entry
- Severe peripheral neuropathy
- Active, untreated infections
- Other cancers except basal/squamous cell of the skin or cervical cancer
- Prior use of paclitaxel
- More than seven days of radiation treatment prior to study entry

Location:

LAC-USC Medical Center
Norris Cancer Hospital
Byron Espina
(323) 865-0371

89. KS Treatment: SU5416

Title:

5416.003: A Multicenter, Dose-Escalating Study in Patients With Cutaneous AIDS-Related Kaposi's Sarcoma

Type of treatment:

SU5416: antitumor

Purpose:

To see if SU5416 is safe, well-tolerated and effective in treating Kaposi's sarcoma of the skin.

About the study:

This is a dose-escalating study. This means that the first patients to enroll in the study will receive the lowest dose of SU5416. If no bad side effects are seen, the next group of patients will receive a higher dose, and so forth until the highest dose researchers plan to study has been given or the highest dose that does not cause bad side effects has been found. SU5416 is given by infusion into a vein twice a week for four weeks (one cycle). Patients who have not experienced bad side effects and who seem to be responding to the medication will be permitted to continue receiving SU5416 in four-week cycles up to one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven KS of the skin
- At least five skin lesions, each of which is at least 10mm long or has been present for at least 30 days and has not been treated with laser therapy or has not been biopsied
- Patients who are taking antiretroviral medicines must be stable (no changes) for at least six weeks prior to study entry and remain on the same therapy throughout this study

Not allowed:

- Women who are pregnant or breastfeeding
- Current uncontrolled serious infections
- Other cancers except basal cell carcinoma of the skin and cervical cancer
- Use of any KS therapy within three weeks of study entry
- Use of erythropoeitin, G-CSF or GM-CSF within two weeks of study entry
- Any surgery within four weeks of study entry

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

New

90. KS Treatment: SU5416

Title:

5416.027: A Multi-Center, Open-Label, Phase II Study of SU5416 in Patients with Therapy-Refractory Cutaneous AIDS-Related Kaposi's Sarcoma

Type of treatment:

SU5416: antitumor

Purpose:

To see if SU5416 is effective in treating KS lesions that have not responded to prior KS treatment.

About the study:

All patients will receive SH5416 by infusion into a vein twice a week for four weeks (one cycle). Patients will be treated for two cycles and those patients who do not experience bad side effects from SU5416 may continue to receive treatment for up to one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Biopsy-proven KS that has not responded to a previous approved KS treatment
- Either at least five measurable KS lesions present for at least 30 days and not previously treated with laser therapy or biopsied **or** KS-related generalized edema or edema of the extremities without evidence of skin lesions

Not allowed:

- Insulin-dependent diabetes
- Use of any investigational drugs within three weeks prior to study entry
- Any surgeries within four weeks prior to study entry
- Other active cancers
- Any KS therapy within two weeks prior to study entry

Location:

HIVCare,
Saint Francis Memorial Hospital
Mark Bowers
(415) 353-6215

91. Human Herpesvirus 8 Project: Developmental

Title:

Pilot Project for the Development of a Branched-Chain DNA Assay for Human Herpes Virus 8

Type of treatment:

Observational: none

Purpose:

To see whether a laboratory test can be developed to detect and measure the amount of human herpes virus 8 in patients' blood samples.

About the study:

Patients with KS will be asked to provide one blood sample at one visit. **Patients will be paid $25 for this one visit.**

Required:

- CD4 cell (T-cell) range: not specified
- At least 13 years old
- Must have a diagnosis of Kaposi's sarcoma

Not allowed:

- No exclusions

Location:

Marin County Specialty Clinic
Alison Clayton
(415) 499-7377

92. KS: Observational

Title:

BRL-002: The Establishment of Kaposi's Cell Lines From Volunteer Patient Punch Biopsy Specimens

Type of treatment:

Observational: none

Purpose:

To collect KS lesion cells to be grown in the laboratory and used to measure response to radiation and other possible treatments.

About the study:

Patients will have some tissue removed from one of their KS lesions. The site will be cleaned and numbed and a small piece of KS lesion will be removed by a small incision. Patients will receive a single stitch and dressing and be asked to return in one week to have the stitch removed and the site inspected for any sign of infection. **Patients will receive a check for $25 within one month of the procedure** for participating in this project. Patients will be required to give their name, address and Social Security number.

Required:

- KS of the skin

Not allowed:

- No exclusions

Location:

UC Davis Cancer Center
Cheri Koppe
(916) 734-3604

93. Kaposi's Sarcoma, Human Herpesvirus 8 Study: Observational

Title:

Kaposi's Sarcoma-Associated Herpesvirus (Human Herpesvirus 8) in Men Who Have Sex With Men

Type of treatment:

Observational: none

Purpose:

To see how human herpesvirus 8 is transmitted between gay men and to see what happens to gay men once they have been infected with the virus. To see how the body uses its immune system to fight the herpesvirus.

About the study:

Participating men will find out if they are infected with human herpesvirus 8 at the first visit. Study visits are every four to six months and the study will last for three years. Study visits will include a short questionnaire as well as donating blood and saliva samples. Patients will also have their HIV viral load and T-cell counts tested. **Patients will be paid $30 for each visit** and all visits are conducted at the General Clinical Research Center at San Francisco General Hospital.

Required:

- CD4 cell (T-cell) range: not applicable
- Age less than 40 years **or** men with KS at any age
- HIV positive men who have sex with men
- Willingness to come to study visits every four to six months for the next three years

Not allowed:

- Females

Location:

UCSF HHV-8 Study
Susan Burns
(510) 642-7743

94. Lymphoma, AIDS-Associated Treatment: 90Y-Lym-I

Title:

UCD-RT0301: Immunotherapy of AIDS-Associated Lymphoma With 90Y-Lym-1

Type of treatment:

90Y-Lym-1: radiation therapy

Purpose:

To see if 90Y-Lym-1 is a safe and effective treatment for AIDS-associated lymphoma.

About the study:

All patients in this study will receive 90Y-Lym-1. 90Y-Lym-1 is given by infusion into a vein. Infusions are given every four weeks for 12 weeks. Patients will be in this study until their lymphoma progresses.

Required:

- CD4 cell (T-cell) range: at least 25
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Diagnosed with AIDS-associated lymphoma

Not allowed:

- Any other cancers within the last five years, except non-melanoma skin cancer and KS of the skin
- Women who are pregnant or breastfeeding

Location:

UC Davis Cancer Center
Patrice Wilbur
(916) 734-3787

95. Non-Hodgkin's Lymphoma Treatment: Chemotherapy, Gene-Therapy

Title:

105: A Phase I/II Study of the Safety and Feasibility of RevM10 or RevM10/Antisense Pol 1 Transduced Hematopoietic Stem Cells (HSC) in HIV-1 Related Non-Hodgkin's Lymphoma Patients Already Being Treated With High Dose Chemotherapy and Peripheral Blood Stem Cell Support

Type of treatment:

REVM 10: gene therapy

Purpose:

To see if it is safe and effective to give genetically altered blood cells to patients who have failed to achieve a complete remission after four cycles of chemotherapy or who have relapsed after demonstrating a response to either initial or salvage therapy for non-Hodgkin's lymphoma. To see if this treatment has any antiretroviral effect on HIV.

About the study:

Patients will undergo chemotherapy and also receive injections of G-CSF (Neupogen) to mobilize the stem cells (undeveloped blood cells). When the white blood cell count is high enough, patients wil undergo apheresis, a process by which stem cells are removed and the remaining blood cells and plasma are returned to the patient. The stem cells are taken to the laboratory where the RevM10 gene or the RevM10/antisense pol 1 gene is added to the patient's stem cells. The stem cells are then returned to the patient by infusion into a vein. Patients wil be followed for response, duration of response and disease-free survival.

Required:

- CD4 cell (T-cell) range: more than 50
- Viral load range: less than 110,000 copies/mL
- HIV positive
- At least 18 years old
- Diagnosis of non-Hodgkin's lymphoma with poor prognosis after the first chemotherapy-induced remission **or** any patients who respond but fail to achieve complete remission aftrer four cycles of standard chemotherapy

Not allowed:

- Any other cancers except KS of the skin (less than six lesions) currently or in the past
- Use of interleukins, interferons, growth hormone, G-CSF, megace or anabolic steroids within 30 days of study entry
- Leukopheresis within 90 days of study entry
- Acute opportunistic infections within 30 days of study entry
- Alcohol and/or substance abuse within the last six months
- Use of any investigational drugs within 30 days of study entry
- Women who are pregnant or breastfeeding

Location:

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

96. Non-Hodgkin's Lymphoma Treatment: DaunoXome

Title:

DaunoXome In the Treatment of HIV-Associated Refractory or Relapsed Non-Hodgkin's Lymphoma (Phase II)

Type of treatment:

DaunoXome: chemotherapy

Purpose:

To see if DaunoXome is safe and effective in treating non-Hodgkin's lymphoma in patients that have tried at least one other treatment with no response and/or for patients who have relapsed after treatment.

About the study:

All patients enrolling in this study will have tried at least one other potential treatment or have relapsed after using that treatment. All patients will receive DaunoXome. DaunoXome is given by infusion into a vein. Medication is given every three weeks. This study will last indefinitely. Patients are required to have a bone marrow biopsy for this study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: not applicable
- HIV positive
- At least 18 years old
- Confirmed diagnosis of intermediate or high grade non-Hodgkin's lymphoma
- Patients must have received at least one potential treatment for non-Hodgkin's lymphoma

Not allowed:

- Any chemotherapy, radiation or hormone therapy must have been discontinued for at least two weeks prior to enrollment
- Patients with CNS lymphoma
- Women who are pregnant or breastfeeding
- Any active AIDS-defining opportunistic infection within two weeks prior to enrollment, except herpes simplex or oropharyngeal candidiasis (thrush)
- Cardiac conditions such as atrial arrhythmias, unstable angina, or myocardial infarction, congestive heart failure, coronary artery bypass or coronary angiopasty
- Any cancers other than skin, cervical, or KS of the skin

Location:

LAC-USC Medical Center
Norris Cancer Hospital
Byron Espina
(323) 865-0371

97. Non-Hodgkin's Lymphoma Treatment: Ifosfamide/Etoposide, Interleukin-2, Interleukin-12

Title:

AMC008: A Randomized Pre-Phase II Trial of Interleukin-2, Interleukin-12, or No Additional Therapy Following Response to Ifosfamide/Etoposide Chemotherapy for Refractory HIV-Associated Non-Hodgkin's Lymphoma

Type of treatment:

Etoposide: chemotherapy
Ifosfamide: chemotherapy
Interleukin-12: immune modulator
Interleukin-2: immune modulator

Purpose:

To see if interleukin-2 and interleukin-12 are safe and effective as maintenance therapy for non-Hodgkin's lymphoma.

About the study:

All patients will receive ifosfamide and etoposide chemotherapy. Patients who have complete or partial remission after a minimum of four chemotherapy cycles will be assigned by chance to one of the following maintenance treatments: interleukin-2 injections twice a day for five days every four weeks; interleukin-12 injections twice a week; or no further therapy. Patients will know which treatment they are receiving. Interleukins are given by injection under the skin. Patients will receive maintenance treatment for six months. Study visits are once a month during maintenance therapy and the study lasts two years.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 70 years old
- Diagnosis of non-Hodgkin's lymphoma
- Failure to respond to or relapse from standard chemotherapy

Not allowed:

- CNS lymphoma
- Active opportunistic infections requiring antibiotic treatment
- Past or current other cancers except cervical or non-melanoma skin cancer
- Use of any immunomodulators, such as interferons or interleukins within two weeks of study entry
- Treatment failure after more than two previous treatments with standard chemotherapy
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center
Norris Cancer Hospital
Byron Espina
(323) 865-0371

University of Southern California AMC
Lenny Africano, PA-C
(323) 343-8264

98. Non-Hodgkin's Lymphoma Treatment: Melphalan, Etoposide, Cyclophosphamide

Title:

98351: (9803) A Trial of Autologous Stem Cell Transplantation as Treatment for HIV-Related Lymphoma

Type of treatment:

Cyclophosphamide: chemotherapy
Etoposide: chemotherapy
Melphalan: chemotherapy

Purpose:

To see if intensive chemotherapy combined with stem cell rescue is safe and well-tolerated in the treatment of AIDS-related lymphoma. To find the highest dose of melphalan that can be given along with stem cell transplants.

About the study:

After two standard cycles of chemotherapy, all patients will receive chemotherapy consisting of cyclophosphamide and etoposide. Starting on Day 5, patients will also receive G-CSF by injection under the skin in order to mobilize stem cells (undeveloped blood cells). When the white blood cell count is high enough, patients will undergo apheresis, a process by which stem cells are removed from the blood and the remaining blood cells and plasma are returned to the patient. When the stem cell collection is complete, patients will have a four-week rest period. Patients will then receive high-dose melphalan followed by their own stem cells. Melphalan is given by infusion into a vein and the first group of patients will receive the lowest dose. If no bad side effects are seen, the next group of patients will receive a higher dose of malphalan with their stem cell infusions, and so forth until the highest dose of melphalan has been given that researchers plan to study or the highest dose that does not cause bad side effects has been found. The screening period will include such tests as blood studies, lumbar puncture (spinal tap), bone marrow exams and CAT scans. Study visits are once a month for the first three months: every three months for one year; then every six months for the second year; then once a year thereafter. The study lasts indefinitely.

Required:

- CD4 cell (T-cell) range: more than $200mm^3$ with any viral load **or** more than $100mm^3$ with a viral load of less than 500 copies/mL
- Viral load range: see above
- HIV positive
- Between 18 and 60 years old
- Diagnosis of intermediate/high grade non-Hodgkin's lymphoma
- Lymphoma has responded to chemotherapy with either partial or complete remission

Not allowed:

- More than two cycles of chemotherapy prior to study entry
- Active opportunistic infections
- CNS lymphoma
- Previous cancers other than basal cell carcinoma of the skin or KS of the skin
- Current hepatitis B
- Prior episodes of PCP, CMV disease, cryptosporidium, toxoplasmosis, disseminated fungal infections, or KS of the internal organs

Location:

UCSF Bone Marrow Transplant Program
Willis Navarro, MD
(415) 476-1421

99. Non-Hodgkin's Lymphoma Treatment: PEG L-Asparaginase

Title:

17NHL-96-3: A Phase I Study of PEG L-asparaginase in the Treatment of Refractory/Relapsed AIDS-Related Non-Hodgkin's Lymphoma (AIDS-NHL)

Type of treatment:

L-Asparaginase:

Purpose:

To see if PEG L-Asparaginase is safe and to determine the maximum dose that is tolerated in patients who have relapsed NHL or are not responding to other treatment. To see how PEG L-asparaginase is processed by the body. To see what level of anti-tumor response PEG L-asparaginase has.

About the study:

This is a dose-ranging or dose-escalating study. This means that the first patients to enroll on the study will receive the lowest dose of PEG L-asparaginase. If this dose is found to be well-tolerated, the next group of patients will receive a higher dose. This procedure is followed until the highest dose of PEG L-asparaginase that researchers plan to study has been given **or** the highest dose is found which does not cause bad side effects. PEG L-asparaginase is given by injection into a muscle. Patients will receive injections every two weeks until they develop intolerable side effects **or** they have complete remission (disappearance of lymphoma) **or** they choose to stop the treatment. Study visits are every two weeks and the study lasts at least one month. Patients will be required to have a lumbar puncture (spinal tap), CT scan of the head and bone marrow biopsy at the beginning of the study.

Required:

- CD4 cell (T-cell) range: not applcable
- Viral load range: not applicable
- HIV positive
- At least 17 years old
- Diagnosis of non-Hodgkin's lymphoma that has come back **or** never gone away with prior exposure to any chemotherapy or radiation treatment

Not allowed:

- Acute intercurrent infection
- Patients with other cancers except basal cell carcinoma, cervical cancer, or KS of the skin, not requiring systemic chemotherapy
- CNS lymphoma
- Past or current pancreatitis
- Treatment with chemotherapy or radiation therapy within two weeks of study entry
- Prior use of L-asparaginase
- Women who are pregnant or breastfeeding

Location:

LAC-USC Medical Center
Norris Cancer Hospital
Byron Espina
(323) 865-0371

University of Southern California AMC
Suzanne Cabriales, RN
(323) 343-8270

100. Non-Hodgkin's Lymphoma Treatment: Rituximab, CHOP Chemotherapy

Title:

AMC010: Randomized Trial of CHOP Chemotherapy With or Without Rituximab (Chimeric Anti-CD20 Antibody) for HIV-Associated Non-Hodgkin's Lymphoma

Type of treatment:

Chemotherapy, systemic: chemotherapy
Rituxan: monoclonal antibody

Purpose:

To see if rituximab is effective in treating non-Hodgkin's lymphoma when combined with CHOP chemotherapy compared to CHOP chemotherapy alone. To see if rituximab is effective as maintenance therapy. To see if rituximab has any effect on HIV viral load and immune function.

About the study:

Patients are assigned by chance to receive CHOP chemotherapy plus rituximab or to receive CHOP chemotherapy alone. All patients will receive CHOP chemotherapy once every 21 days (one cycle) for four to six cycles. Patients will have a minimum of four cycles or two cycles beyond the documentation of a complete response. Rituximab is given by infusion into a vein on Day 1 of each chemotherapy cycle. Following the completion of chemotherapy, patients will receive maintenance therapy with rituximab every 28 days beginning with the 28th day of the final chemotherapy cycle for three months Patients will be followed for respose, duration of response and disease-free survival.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Documented B-cell non-Hodgkin's lymphoma
- Tumors must be CD20 positive

Not allowed:

- CNS lymphoma
- Active opportunistic infections requiring antibiotic treatment. Patients with MAC are **not** excluded
- Women who are pregnant or breastfeeding
- Past or current cancers excluding cervical, non-melanomatous skin cancer or KS not requiring systemic chemotherapy
- Past treatment with chemotherapy or radiation

Location:

AIDS Oncology Practice
at UCSF / Mt. Zion
Barbara Klencke, MD
(415) 567-5581

LAC-USC Medical Center
Norris Cancer Hospital
Byron Espina
(323) 865-0371

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

UCSF Positive Health Practice
at SFGH/ICTG
Ron Frianeza
(415) 476-9296 ext. 316

University of Southern California AMC
Lenny Africano, PA-C
(323) 343-8264

101. Non-Hodgkin's Lymphoma and HIV Treatment: Chemotherapy, Ribozyme Gene Therapy

Title:

17NHLK-97-2: High Dose Chemotherapy and Autologous Peripheral Stem Cell Transplantation for HIV Lymphomas: A Phase IIa Study of Comparative Marking Using a Ribozyme Gene and a Neutral Gene

Type of treatment:

Anti-HIV Ribozyme: gene therapy
Chemotherapy, systemic: chemotherapy

Purpose:

To see if genetically-engineered cells that are resistant to HIV can be safely given to lymphoma patients currently undergoing high-dose chemotherapy. To see if these altered cells can mature and circulate in the bloodstream. The therapeutic gene used in this study is called a ribozyme.

About the study:

Patients who are undergoing chemotherapy for non-Hodgkin's lymphoma will take their chemotherapy along with G-CSF for eight days to mobilize the stem cells (undeveloped blood cells). After eight days, patients will give blood samples by a process called apheresis, by which stem cells are removed. The remaining blood cells and plasma are returned to the patient. The stem cells are taken to the laboratory and the patient's $CD34^+$ cells are separated from the stem cells. Half the patient's $CD34^+$ cells will receive the gene containing the anti-HIV ribozyme and half the cells will receive a neutral gene. The $CD34^+$ cells are then returned to the patient by infusion into a vein. Study visits are every three months for the first year, then every six months for the second year. Patients will then be seen once a year for an indefinite period of time.

Required:

- CD4 cell (T-cell) range: at least 100 at the time of lymphoma diagnosis
- Viral load range: less than 10,000 copies/mL
- HIV positive
- Between 18 and 60 years old
- Must be on at least two antiretrovirals. AZT may not be used because of its bone marrow toxicity
- Biopsy-proven non-Hodgkin's lymphoma, intermediate or high grade
- Demonstrated complete or partial remission with chemotherapy

Not allowed:

- Women who are pregnant or breastfeeding
- Any prior cancers other than basal cell carcinoma of the skin
- Evidence of active CNS lymphoma
- Prior CMV disease, such as retinitis or gastritis
- Bacterial or fungal infections requiring antibiotics within 14 days of study entry
- Any opportunistic infections within the past year (such as PCP, toxoplasmosis, MAC, or cryptosporidiosis) or evidence of dementia or encephalopathy
- Active hepatitis B and/or antibody positive for hepatitis C

Location:

LAC-USC Medical Center
Norris Cancer Hospital
Byron Espina
(323) 865-0371

102. MAC Prevention: Observational

Title:

ACTG 393: A Study of Discontinuing Maintenance Therapy in Subjects with Disseminated Mycobacterium Avuim Complex (DMAC)

Type of treatment:

Observational: none

Purpose:

To see if MAC prevention medications can be stopped in patients who have had MAC before, been treated for at least 12 months, are now free of any signs of MAC for at least 16 weeks, and have a CD4 cell (T-cell) count of 100 or more.

About the study:

Patients enrolling in this study will be required to have a bone marrow biopsy. A bone marrow biopsy is performed by inserting a needle into the hip bone and removing a small piece of bone marrow. Patients will continue to take their MAC prevention medicines for the first six weeks of the study. After six weeks, patients will stop their MAC medications if their MAC blood tests are negative and they show no signs of MAC disease. Patients must continue to take their antiretroviral medications throughout the study. Study visits are at Weeks 6, 10 and 14, then every two months until the end of the study. The study lasts about 27 months.

Required:

- CD4 cell (T-cell) range: at least 100
- HIV positive
- At least 13 years old
- Use of antiretroviral therapy for at least 16 weeks and have made no changes to that therapy for at least eight weeks prior to study entry
- Previous diagnosis of MAC
- Must be on a minimum of two drug anti-MAC therapy for at least 12 months consisting of either clarithromycin or azithromycin plus either ethambutol or rifabutin

Not allowed:

- Signs of MAC disease, such as fever, night sweats, weight loss, diarrhea or liver and/or spleen changes within 16 weeks of study entry
- Use of immunomodulators (interleukins, interferons), corticosteroids, chemotherapy, vaccines, IVIG, or GM-CSF within two months of study entry
- Women who are pregnant or breastfeeding
- Patients requiring the use of azithromycin, clarithromycin, ethambutol or rifampin for the treatment of diseases other than MAC

Location:

Stanford University Medical Center
Debbie Slamowitz, RN
(650) 723-2804

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

University of Southern California ACTU
Frances Canchola, RN
(323) 343-8281

103. Antiretroviral-Associated Nausea and Vomiting Treatment: Marinol

Title:

Marinol for the Treatment of Nausea and Vomiting Associated With Antiretroviral Therapy in Patients with HIV/AIDS

Type of treatment:

Dronabinol: appetite stimulant

Purpose:

To see if Marinol (dronabinol) is safe and effective in treating nausea and vomiting associated with the use of antiretoviral medications in HIV infected patients.

About the study:

Patients are assigned by chance to receive one of two doses of Marinol, either once a day or twice a day. Those patients assigned to take Marinol twice a day will take it within one hour of taking antiretroviral medications. Those patients assigned to take Marinol once a day will take it at bedtime. After the screening and baseline visits, there are two study visits, one at Week2 and one at Week 6. The study lasts six weeks. Some locations may pay patients for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Stable (no changes) antiretroviral therapy for at least two weeks prior to study entry and throughout the study

Not allowed:

- Active opportunistic infections within four weeks of study entry
- Unable to take nutrition by mouth
- Vomiting or diarrhea that is not easily managed by standard treatments
- Use of marijuana within one week of study entry and throughout the study
- Use of narcotics, sedative-hypnotics or tranquilizers
- Active alcohol and/or substance abuse which may interfere with the study
- Women who are pregnant or breastfeeding
- Significant dementia

Location:

ViRx, Inc.
Debbie Hildebrandt
(415) 353-5623

104. PML Treatment: Cidofovir

Title:

ACTG 363: Pilot Study on the Effect of Cidofovir for the Treatment of Progressive Multifocal Leukoencephalopathy (PML) in Patients with Acquired Immunodeficiency Syndrome (AIDS)

Type of treatment:

Cidofovir: antiviral

Purpose:

To see if cidofovir is safe, well-tolerated and effective in treating PML, an infection of the brain caused by JC virus.

About the study:

During the screening period, patients will have an MRI of the brain. An MRI gives a detailed look at the brain. Patients will also have a lumbar puncture (spinal tap). All patients will receive cidofovir. Cidofovir is given by infusion into a vein. Patients will be in the clinic for about six hours on the days they receive cidofovir. Cidofovir is given once a week for the first two weeks, then once every other week until the end of the study. Within two days before each dose of cidofovir, patients will have blood and urine tests as well as an eye exam. At Weeks 4, 8, 12, 16, 20 and 24, patients will have a neurological examination. At Weeks 8 and 24, patients will have another MRI of the brain and another lumbar puncture. The study lasts 24 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Symptoms of PML for 90 days or less
- MRI of the brain showing focal white matter abnormalities
- CSF positive for JCV, or brain biopsy showing PML

Not allowed:

- Acute opportunistic infections other than KS of the skin
- Neurological exam suggesting other conditions, such as stroke, herpes simplex encephalitis or trauma
- CAT scan or MRI that show enhancing mass lesions
- CSF positive for CMV, bacteria, mycobacteria or fungus
- Past or current uveitis
- Past use of cidofovir
- Use of immunomodulators, such as interferons or interleukins, within 90 days of study entry
- Use of IV pentamidine, foscarnet or amphotericin B within seven days of study entry
- Women who are pregnant or breastfeeding
- Use of investigational antiretroviral drugs with activity against viruses other than HIV within 30 days of study entry

Location:

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

105. Peripheral Neuropathy Treatment: Gabapentin

Title:

945-955-245: Randomized, Double-Blind Study Assessing "Low Dose" Versus "High Dose" Gabapentin (Neurontin) for the Treatment of Painful HIV Polyneuropathy

Type of treatment:

Gabapentin: anticonvulsant

Purpose:

To see if Gabapentin is safe and has any effect for treating painful peripheral neuropathy.

About the study:

Patients are assigned by chance to receive one of two doses of Gabapentin. Gabapentin is a pill and taken by mouth. Each of the two doses will be adjusted until significant pain relief or intolerable side effects have been reported by the patients. Study visits are every two weeks and the study lasts a maximum of eight weeks. Some locations may pay individuals for their participation.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 80 years old
- Diagnosis of painful peripheral neuropathy

Not allowed:

- Prior use of Gabapentin

Location:

UCSF Pain Clinical Research Center
Linda Guandalini
(415) 885-7804

New

106. Peripheral Neuropathy Treatment: Lamictal

Title:

LAM 40006:Randomized, Double-Blind, Placebo-Controlled Evaluation of Lamictal (lamotrigine) in HIV-Associated Peripheral Neuropathy

Type of treatment:

Lamictal: antiseizure medication

Purpose:

To see if Lamictal helps relieve the pain of peripheral neuropathy and improves the quality of life in HIV-infected patients.

About the study:

Patients are assigned by chance to receive Lamictal or placebo. Lamictal and its placebo are pills and taken by mouth. Neither patients nor their doctors will know which they are receiving until the study ends. There are six study visits and the study lasts eleven weeks. Patients will have the option to continue taking open label (real) Lamictal for three months. Patients will be paid for each study visit they attend.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 65 years old
- Must have moderate to severe peripheral neuropathy diagnosed by a neurologist
- Patients taking ddI, ddC or d4T must be on stable (no changes) doses for at least eight weeks prior to study entry

Not allowed:

- Women who are pregnant or breastfeeding
- Active opportunistic infections requiring treatment
- Prior use of Lamictal
- Enrollment in another drug study
- Active alcohol and/or substance abuse

Location:

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

UCSF Department of Neurology
Naomi Schoenfeld
(415) 502-5064

New

107. HIV and Tuberculosis: Observational

Title:

ACTG A5062: Viral and Immune Dynamics in HIV-Infected Patients with Tuberculosis

Type of treatment:

Observational: none

Purpose:

To explore what effects occur in the body's immune system when patients are infected with both HIV and tuberculosis and are taking Highly Active Antiretroviral Therapy (HAART).

About the study:

There are two parts to this study. **Part 1** is for patients who are newly diagnosed with tuberculosis and plan to start a new anti-HIV treatment within six months. Part 1 patients will begin taking anti-tuberculosis drugs which must include rifabutin instead of rifampin. Treatment for TB will not be given as part of the study but must be obtained by prescription or by other means. TB treatment must be 'directly observed'. A health care worker will watch patients take their medications either at home or in the clinic every weekday during TB treatment. Study visits are every two weeks for the first month, then once a month for up to 24 weeks. **Part 2** is for patients who have been on anti-tuberculosis treatment and are about to begin a new anti-HIV treatment. Part 2 will include patients with and without TB infection. Treatments for TB and HIV will not be provided by the study and must be obtained by prescription or other means. Patients must start antiretroviral treaments with AZT (or d4T), 3TC and nelfinavir. If patients do not do well on these drugs, they may switch to a new group of drugs. Study visits are once a week for the first month, every two weeks for the second month, once a month until six months, then every two months. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: at least 20,000 copies/mL
- HIV positive
- At least 18 years old

TB Treatment Group

- Newly diagnosed pulmonary tuberculosis, confirmed or suspected
- Must agree to a rifabutin-containing treatment
- Must start HAART treatment within six months of TB treatment

Not allowed:

- Prior use of combination antiretroviral therapy for more than three months. Patients who have already started HAART during this episode of TB are not eligible
- Women who are pregnant or breastfeeding
- Patients who are not able to starting AZT (or d4T), 3TC and nelfinavir

TB Treatment Group

- Suspected multidrug-resistant tuberculosis
- More than 16 weeks of TB therapy for the present episode

Non-TB Infected Patients

- Clinical or radiological evidence of active tuberculosis

Location:

UCSD Treatment Center
Screening Coordinator
(619) 543-8080

108. HIV Wasting Treatment: Serostim

Title:

9037: A Phase IV, Randomized, Parallel Group, Double-Blind, Placebo-Controlled, Dose-Ranging Multicenter Study of Serostim, Mammalian Cell-Derived Recombinant Human Growth Hormone (r-hGH[m]), in the Treatment of HIV-Associated Catabolism/Wasting

Type of treatment:

Serostim: human growth hormone

Purpose:

To see if Serostim is effective in changing physical functioning capabilities in patients with AIDS wasting. To see which dose of Serostim works best to change lean body mass.

About the study:

Patients are assigned by chance to receive one of two doses of Serostim or placebo for the first twelve weeks of the study. After 12 weeks, those patients assigned to receive placebo will be assigned by chance to receive one of the two doses of Serostim. Neither patients nor their doctors will know which they are receiving until the study ends. Serostim is an injection given under the skin and will be given in the evening (preferably at bedtime). Patients and/or caregivers will be taught how to give injections. Body composition, physical function and quality of life will be evaluated at Weeks 12, 24 and 48. The study lasts about one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Diagnosis of AIDS wasting defined as: unintentional weight loss of at least 10% **or** weight less than 90% of ideal body weight
- Must be receiving at least 100% of the estimated caloric requirement based on a formal nutritional analysis (to be done by the research staff)
- Must be taking an approved antiretroviral therapy for at least 8 weeks prior to study entry and no changes to this treatment during the first 12 weeks of the study

Not allowed:

- Current active opportunistic infections or malignancies, except KS of the skin
- Prior pancreatitis, carpal tunnel syndrome, glucose intolerance; angina, moderate to severe edema, coronary artery disease
- Women who are pregnant or breastfeeding
- Use of radiation therapy, chemotherapy, glucocorticords, or interferons
- Chronic diarrhea, defined as 6 or more liquid stools per day
- Unstable or untreated hypertension
- Active alcohol or substance abuse

Location:

Cedars-Sinai Medical Center
Morgan Knapp, RN
(310) 423-3755

Kaiser Permanente Clinical Trials Unit, San Francisco
Tye Luu, RN
(415) 202-4671

UCLA CARE Center
Christine MacNaughton
(310) 206-6414

ViRx, Inc. - Palm Springs
Vangie Weems
(760) 864-6266

109. HIV Wasting Treatment: Serostim

Title:

IMP 21020: A Pilot, Multicenter, Open Label Study to Determine the Efficacy and Safety of Serostim in HIV Patients With Unintentional Weight Loss or BCM Depletion on Combination Antiretroviral Therapy With or Without Protease Inhibitors

Type of treatment:

Serostim: human growth hormone

Purpose:

To see if Serostim is safe and effective in treating HIV wasting in patients who are taking combination antiretroviral therapy with or without a protease inhibitor.

About the study:

All patients will receive Serostim; there are no placebos in this study. Serostim is given by an injection under the skin each night. Patients and/or caregivers wil be taught how to give injections. Study visits are at Weeks 2, 6, 12 and then every three months. Study visits will include blood tests, physical exams and body composition analysis using BIA. The study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- AIDS wasting with at least one of the following:
  -unintentional weight loss of at least 5% over a period of two weeks to 12 months **or**
  -weight less than 95% of ideal body weight **or**
  -in the absence of unintentional weight loss of 5%, body cell mass loss of 3-5%

Not allowed:

- Current pancreatitis, carpal tunnel syndrome, glucose intolerance, angina pectoris, coronary artery disease, or any disease associated with moderate to severe edema
- Any active cancers
- Chronic diarrhea, defined as six or more liquid stools per day

Location:

Kaiser Permanente - Los Angeles
Mitzi St. Ange, RN
(323) 783-8959

110. HIV Wasting Treatment: Thalidomide, Serostim

Title:

Mitigation of Episodic Wasting in HIV Infection

Type of treatment:

Serostim: human growth hormone
Thalidomide: cytokine inhibitor, antiwasting

Purpose:

To see if growth hormone or thalidomide can prevent episodic wasting in HIV patients during secondary infections.

About the study:

Patients are assigned by chance to receive thalidomide or growth hormone or placebo. All patients will receive capsules and daily injections. Neither patients nor their doctors will know which they are receiving until the study ends. Patients will take study medications for four weeks and have five study visits to the General Clinical Research Center at San Francisco General Hospital for body weight, energy expenditure and protein synthesis rate measurements. **Patients will be paid $500 for completing the study.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- New diagnosis of one of the following: bacterial pneumonia, sinusitis or bronchitis; pyelonephritis; PCP; tuberculosis, MAC; cryptococcal pneumonia or meningitis; histoplasmosis or cellulitis
- Patients must enroll in the study within three days of beginning treatment for a bacterial infection or within five days of beginning treatment for mycobacterial or fungal infection

Not allowed:

- Women who are pregnant or breastfeeding
- Use of anabolic agents such as growth hormone or steroids (except stable testosterone replacement)
- Any cancers other than KS of the skin
- Moderate to severe peripheral neuropathy
- Uncontrolled high blood pressure, diabetes or congestive heart failure

Location:

UCSF/SFGH Endocrinology
Heather Algren, RN
(415) 206-3319

New

111. HIV Weight Loss Treatment: Oxandrolone

Title:

M017: An Open-Label Evaluation of the Effects of Oxandrolone (Oxandrin) on Body Weight and Composition in Patients with HIV-Associated Weight Loss: Definition of Variables Predictive of Response to Treatment

Type of treatment:

Oxandrolone: anabolic steroid

Purpose:

To see if oxandrolone has any effect on body weight and body composition in HIV-infected patients with involuntary weight loss.

About the study:

All patients will take oxandrolone. There are no placebos in this study. Oxandrolone is a pill and taken by mouth twice a day. Study visits are every two months and the study lasts four months.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Involuntary weight loss defined as: 95% or less of ideal body weight **or** 3% loss of weight within one month, 5% loss of weight within 6 months **or** 10% loss of weight within 12 months
- Patients on antiretroviral therapy must be on stable (no changes) treatment for at least on month prior to study entry

Not allowed:

- Uncontrolled opportunistic infections
- Any cancers other than KS of the skin within the past year
- Women who are pregnant or breastfeeding Any condition that limits ingestion of nutrients, such as oral, throat or esophageal disorders
- Chronic uncontrolled diarrhea defined as more than three stools per day for more than four days per week for at least two weeks.

Location:

Kaiser Permanente Clinical Trials Unit, San Francisco
Brooke Anderson, RN
(415) 202-3487

112. HIV Weight Loss: Observational

Title:

Energy Balance and Wasting Syndrome

Type of treatment:

Observational: none

Purpose:

To study metabolism and collect data from patients with HIV weight loss.

About the study:

Patients joining this study should be experiencing some weight loss associated with HIV disease. There are two options for this study, inpatient or outpatient. The inpatient study requires four days in the hospital for metabolic rate testing and two outpatient visits. **The inpatient study lasts three weeks and patients will be paid $400 for completing the study. The outpatient study requires three days of outpatient visits one week apart and those patients will be paid $250 for completing the study.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Male patients only

Not allowed:

- Females

Location:

San Francisco VA Medical Center
Mae Pang, RN, MS
(415) 750-2005

113. Anabolic Therapies and Metabolism: Serostim, Nandrolone Decanoate

Title:

Anabolic Therapies and their Metabolic Effects in AIDS

Type of treatment:

Nandrolone Decanoate: anabolic steroid
Serostim: human growth hormone

Purpose:

To evaluate the effects of growth hormone and nandrolone decanoate on regional fat content, sugar and fat metabolism, HIV viral load, and thymus function in HIV-infected patients who have experienced alterations in their body shape.

About the study:

Patients who have experienced changes in the shape of their bodies will be evaulated by an endocrinologist to see if they are eligible. Eligible patients will be hospitalized in the General Clinical Research Center at San Francisco General Hospital for five days to undergo detailed sugar and fat metabolism studies and to measure total and regional fat content. After completing these tests, patients will begin a six-month treatment course of either nandrolone decanoate or growth hormone. Patients will know which treatment they are receiving. Patients will return to the General Clinical Research Center periodically for follow-up. The study lasts at least six months and **patients will be paid $1,200 for completing the study.**

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: average of two values must be less than 5,000 copies/mL when measured twice in the preceeding month
- HIV positive
- Evidence of fat accumulation, such as abdominal obesity or buffalo hump in the neck and/or peripheral fat loss (lipodystrophy)
- Between 30 and 50 years old

Not allowed:

- Diabetes mellitus
- History of cardiovascular disease
- Use of testosterone, DHEA, megace, thalidomide, ketoconazole, lipid-lowering medicines, hypoglycemic medicines, growth hormone or nandrolone decanoate within 30 days of study entry

Location:

UCSF/SFGH Endocrinology
Joan Lo, MD
(415) 206-4430

114. Metabolism and Protease Inhibitor Therapy: Observational

Title:

Effects of Initiation of Protease Inhibitor Therapy on Metabolism and Body Composition

Type of treatment:

Observational: none

Purpose:

To see what effects protease inhibitors have on sugar and fat metabolism and on body composition in patients who are starting protease inhibitor treatment.

About the study:

Patients who are about to start treatment with a protease inhibitor will be hospitalized in the General Clinical Research Center at San Francisco General Hospital for five days of detailed studies of sugar and fat metabolism and measurements of total and regional fat content. After completing these measurements, patients will begin their antiretroviral treatment, which includes a protease inhibitor and return to the General Clinical Research Center periodically over the next 18 months for follow-up measurements. **Patients will be paid $2,000 for completing this study.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 18 years old
- Body mass index less than 27 kg/m2 (to be calculated by research staff)

Not allowed:

- Women who are pregnant or breastfeeding
- Prior use of any protease inhibitors
- Diarrhea, defined as 6 or more stools per day
- Persistent nausea or vomiting
- Diabetes mellitus
- Use of anabolic medicines, appetite stimulants, parenteral or tube feeding, or initiation of treatment for a systemic infection within 30 days of study entry. Patients on stable testosterone replacement therapy for at least 60 days prior to study entry are allowed.

Location:

UCSF/SFGH Endocrinology
Kathleen Mulligan, PhD
(415) 206-5882

115. Nutrition in Women with HIV: Observational

Title:

Nutritional Assessment of Women Living with HIV

Type of treatment:

Observational: none

Purpose:

To learn about the effect of HIV disease on women's body composition (fat, muscle and bone). To learn how HIV disease affects the amount of energy used up by a woman's body when it is at rest. To learn how HIV disease affects women's eating habits. To compare these factors in women and men.

About the study:

This study consists mainly of body measurements and interviews. Every six months, patients come into the clinic for a two-hour study visit. Tests and measurements are done to determine body composition and patients are asked questions about the kind and amount of food they eat. Nutritional counseling is offered to patients who want it. The study lasts for an indefinite length of time. **Patients are paid $25 at each visit.**

Required:

- CD4 cell (T-cell) range: not specified
- HIV positive
- Female

Not allowed:

- Males

Location:

UCSF/SFGH Endocrinology
Viva Tai, RD, MPH
(415) 206-4090

116. Pharmacokinetics in Women: AZT, Oral/ Injectable Contraceptives

Title:

ACTG 317: The Effect of Oral and Injectable Contraceptives (Norethidrone/Ethinyl Estradiol, Medroxyprogestrone Acetate) and Gender on Plasma and Intracellular Zidovudine Pharmacokinetics

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Depo-Provera: injectable contraceptive
Ortho Novum: oral contraceptive

Purpose:

To see if mens' and womens' bodies process AZT differently (Part A). To see if taking birth control pills or an injectable birth control agent has any effect on the way AZT is processed by womens' bodies (Part B).

About the study:

Both men and women will participate in Part A. All patients will take AZT by mouth three times a day, along with their other antiretroviral medications, for the first seven days. On Day seven, some patients will receive AZT through a vein in the morning and two doses of AZT by mouth later in the day. On Day 8, those patients who took AZT by

mouth on Day 7 will take AZT through a vein in the morning and two doses by mouth later in the day. On the day they receive AZT through a vein (either Day 7 or Day 8), multiple blood and urine tests will be collected throughout the day. Male patients will discontinue study treatment and return for a final visit within seven days after Day 8. Females will resume their pre-study medication(s) and move on to Part B. Women in Part B will choose either oral (Ortho Novum 1/35) or injectable (Depo-Provera) contraceptive and begin taking it at the onset of their next menstrual cycle following Part A. Between Days 7-11 after the start of their NEXT menstrual period (after beginning birth control), women will resume taking AZT as they did in part A with a dose of AZT given through a vein either on Day 7 or Day 8 and have the same blood and urine tests as in part A. Women will return for a final visit within seven days of Day 8. **The study is currently enrolling females only.**

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 18 and 45 years old
- At least 60 days or more of therapy with AZT alone or in combination with 3TC, ddI, ddC, or 3TC + indinavir, up to seven days prior to study entry
- Women must have regular menstrual cycles, defined as a 25-35 day interval with usual amounts of bleeding
- Women must enter Part A between 10-18 days since the first day of their last menstrual period (LMP)

Not allowed:

- Women receiving oral or injectable contraceptives for the past three months
- Current use of any NNRTIs, such as delavirdine, nevirapine or efavirenz
- Past intolerance of 600mg/day AZT
- Past or current hypertension (> 140/90 mm Hg)
- Past thrombophlebitis or pulmonary emboli
- Any cancers including KS

Location:

UCSF Positive Health Practice
at SFGH/ACTU
Marc Gould
(415) 514-0550 ext. 362

117. Pharmacokinetics: Cyclosporin, Protease Inhibitors

Title:

Study of the Pharmacokinetic Interaction Between Cyclosporin and Protease Inhibitors in Individuals Living with HIV

Type of treatment:

Cyclosporin: immune suppressor

Purpose:

To see how cyclosporin is processed by the body when taken along with protease inhibitors. This information may help doctors and pharmacists to prescribe cyclosporin for HIV-infected patients who are also taking protease inhibitors.

About the study:

Participants will be required to stay in the General Clinical Research Center at UCSF for 48 hours for multiple blood draws. On the first morning, participants will receive one dose of cyclosporin by infusion into a vein. On the second morning, participants will receive a second dose of cyclosporin capsules taken by mouth. **Patients will be paid $300 after completing the study.**

Required:

- CD4 cell (T-cell) range: more than 200
- Viral load range: must be undectectable
- HIV positive
- Must be on stable (no changes) treatment that includes a protease inhibitor for at least one month prior to study entry

Not allowed:

- Active opportunistic infections

Location:

UCSF Biopharmaceutical Sciences
Leslie Floren, Pharm.D.
(415) 502-4949

118. Pharmacokinetics: Procaine Hydrochloride (Anticort)

Title:

511-101PK: A Pharmacokinetic and Safety Study of Procaine Hydrochloride in HIV Infected Patients

Type of treatment:

Procaine Hydrochloride: immune modulator

Purpose:

To see if procaine hydrochloride (Anticort) is safe when given orally to HIV positive patients. To see how procaine hydrochloride is processed by the body.

About the study:

This is a dose-escalating or dose-ranging study. This means the the first group of patients to enroll will receive the lowest dose of procaine hydrochloride. If no bad side effects are seen, the next group of patients will receive a higher dose and so forth until the highest dose researchers plan to study has been given or the highest dose that does not cause bad side effects has been found. Procaine

hydrochloride (Anticort) is a pill and taken by mouth. Six HIV negative volunteers will also be enrolled but will not receive any study drug, they will only have a blood and urine test. Study visits are once a week and the study lasts eleven weeks.

Required:

- CD4 cell (T-cell) range: more than 200
- Viral load range: not applicable
- HIV positive, except for six negative volunteers
- At least 18 years old
- Stable (no changes) antiretroviral therapy for at least eight weeks prior to study entry

Not allowed:

- Current use of any experimental medications or immunomodulators (interferons or interleukins)
- Active opportunistic infections
- Use of erythropoietin (Procrit) during the study
- Patients with adrenal insufficiency (to be determined at screening)
- Patients using DHEA, ketoconazole, Bactrim/Septra, or anti-cholinesterase inhibitors for glaucoma

Location:

AIDS Research Alliance
Corie Castro
(310) 358-2429

119. Pharmacokinetics: Rifampin

Title:

Pharmacokinetics of Antituberculous Agents in HIV

Type of treatment:

Rifampin: antimycobacterial

Purpose:

To learn how rifampin is absorbed and processed in the bodies of women with AIDS who are not taking protease inhibitors.

About the study:

This study is open to women with AIDS who are not taking protease inhibitors. All patients take 600 mg. of rifampin every day for five days. Blood is drawn to measure the amount of rifampin in the blood. A small tube is inserted into the lungs to collect fluid and cells in order to measure the amount of rifampin that is absorbed into the lungs. There are several short study visits and one six-hour study visit. **Patients are paid $350 for completing the study.**

Required:

- CD4 cell (T-cell) range: not specified
- At least 18 years old
- Diagnosis of AIDS
- Negative PPD (skin test for TB), negative chest x-ray for patients with HIV
- Females only

Not allowed:

- Diarrhea, abdominal pain or cramping, nausea, vomiting
- Women who are pregnant or breast-feeding
- Current use of any protease inhibitors

Location:

UCSF Infectious Diseases Research
Juliana Kipps, RN
(415) 476-5398

New

120. Pharmacokinetics in HIV-Negative Volunteers: Amprenavir, Efavirenz

Title:

ACTG A5043: Pharmacokinetic Interaction Studies of Amprenavir (APV, 141W94), Efavirenz (EFV, DMP-266), and a Second Protease Inhibitor in HIV-Seronegative Volunteers

Type of treatment:

Amprenavir: antiretroviral, protease inhibitor
Fortovase: antiretroviral, protease inhibitor
Indinavir: antiretroviral, protease inhibitor
Nelfinavir: antiretroviral, protease inhibitor
Ritonavir: antiretroviral, protease inhibitor
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)

Purpose:

To determine how quickly the combinations of drugs enter the bloodstream and how quickly they begin to leave the blood. To see if these combinations of drugs are safe and well-tolerated in HIV-negative volunteers.

About the study:

Volunteers will take amprenavir (a protease inhibitor) and efavirenz (an NNRTI) for the first two weeks of the study. After two weeks, volunteers will return to the clinic for a 12-hour study visit during which multiple blood samples will be taken throughout the day. During the second two weeks of the study (Part 2), volunteers will continue to take amprenavir and efavirenz and are assigned by chance to one of five groups. Group 1 will continue to take amprenavir and efavirenz alone. Groups 2 - 5 will add

either indinavir or nelfinavir or ritonavir or saquinavir. Participants will know to which group they have been assigned. Volunteers will take these combinations for an additonal two weeks. After two weeks of Part 2, there will be another 12-hour study day for multiple blood testing. A final study visit will be conducted two to three weeks after completing study drugs. The study will last from six to seven weeks.

Required:

- HIV negative
- Between 18 and 65 years old

Not allowed:

- Women who are pregnant or breastfeeding
- Documented or suspected acute hepatitis within 35 days of study entry
- Use of any investigational drugs within 35 days of study entry
- Acute treatment for an illness or infection within 14 days of study entry
- Unexplained fever of more than 38.5 C or 101.3 lasting for seven or more days within 14 days of study entry
- Use of prescription medications within 14 days of study entry. Over-the-counter drugs may be taken as needed up until 48 hours prior to study entry
- Active alcohol and/or substance abuse which may interfere with the study. Alcohol is prohibited the day prior to the 12-hour study day as well as on the 12-hour study day itself
- Any alterations to existing tobacco smoking habits for the duration of the study

Location:

Stanford University Medical Center
Sandra Valle, PA-C
(650) 723-8169

121. Pharmacokinetics in Pregnant Women: HAART

Title:

The Pharmacology of Antiretroviral Therapy During Pregnancy

Type of treatment:

HAART: antiretrovirals, including at least one protease inhibitor

Purpose:

To see how womens' bodies process Highly Active Antiretroviral Therapy during pregnancy.

About the study:

Pregnant women will spend one 8-hour day per trimester at the research clinic for multiple blood draws. Patients will have a catheter inserted into a vein to reduce the number of needle sticks during blood draws. Patients will be on this study for the duration of their pregnancy.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Pregnant, at least six weeks gestation
- Must be taking stable (no changes) Highly Active Antiretroviral Therapy (HAART) that includes at least one protease inhibitor, for at least two weeks prior to study entry

Not allowed:

- Women with a history of a life-threatening event associated with antiretroviral therapy
- Active alcohol and/or substance abuse

Location:

UCSF Drug Research Unit at SFGH
Bradley Kosel, Pharm.D.
(415) 476-6870

122. Mother-Newborn Transmission Prevention: Nevirapine

Title:

Pediatric ACTG 316: A Phase III Randomized, Double Blinded Study of Nevirapine for the Prevention of Maternal-Fetal Transmission in Pregnant HIV-Infected Women

Type of treatment:

Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI

Purpose:

To find out if taking nevirapine during labor prevents infants of HIV-infected mothers from becoming infected with HIV.

About the study:

HIV-infected pregnant women will be assigned by chance to receive nevirapine or placebo during labor. Nevirapine and its placebo are taken by mouth. Women will take a single dose of nevirapine (or its placebo) during active labor. The newborn infant will also receive a single dose of nevirapine (or placebo) between 48 and 72 hours after it is born. Mothers will be encouraged to also take AZT during their pregnancy (in accordance with US Public Health Service guidelines). Mothers and their infants will have follow-up study visits at one month, 3 months and 6 months after the infant is born.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive pregnant women
- At least eight months pregnant

Not allowed:

- Prior use of nevirapine, delavirdine, Sustiva or any other non-nucleoside reverse transcriptase inhibitor
- Participation in any other perinatal treatment study

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCLA Medical Center - Pediatrics
Maryanne Dillon, NP
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Maureen Shannon, FNP / CNM
(415) 206-8919

123. HIV Infection in Pregnant Women and Infants: Nelfinavir, AZT, 3TC

Title:

Pediatric ACTG 353: A Phase I Trial of the Safety, Tolerance and Pharmacokinetics of Oral Nelfinavir (Viracept) Co-Administered with Zidovudine (ZDV) and Lamivudine (3TC) in HIV-Infected Pregnant Women and Their Infants

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor

Purpose:

To see if nelfinavir is safe and effective in treating HIV infection when given in combination with AZT and 3TC to pregnant women. To see how nelfinavir is processed in pregnant womens' bodies and to see how it is processed in the newborn infant.

About the study:

Participants will receive AZT, 3TC and nelfnavir from the start of the study until 12 weeks after delivering their babies. Women will come to the clinic every two weeks until week 36 of their pregnancy, then once a week until the start of labor. Mothers will have ultrasound performed between 18 and 20 weeks of pregnancy and every four weeks after week 26 of pregnancy. After taking study drugs for about two weeks, mothers will have a nine-hour study visit for multiple blood draws. Mothers in active labor will receive their AZT by infusion into a vein. Newborn babies will be taking nelfinavir, AZT and 3TC when they are able to take liquids and continue taking study medications for six weeks. Babies will have study visits at 8 days, 3 weeks, 6 weeks, 3 months and 6 months of life.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Pregnant with a gestational age of at least 14 weeks but no more than 34 weeks, based upon menstrual history and confirmed by ultrasound or sonograph

Not allowed:

- Past use of any protease inhibitors
- Treatment with 3TC prior to pregnancy **or** more than three weeks treatment during this pregnancy
- Use of NNRTIs, such as delavirdine, nevirapine or Sustiva within two weeks of study entry
- Active alcohol or substance abuse
- Active opportunistic infections
- Chronic malabsorption or diarrhea

Location:

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCLA Medical Center - Pediatrics
Maryanne Dillon, NP
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

124. HIV Infection in Pregnant Women: Indinavir, AZT, 3TC

Title:

Pediatric ACTG 358: A Phase I Trial of the Safety,Tolerance and Pharmacokinetics of Oral Indinavir Co-Administered with Lamivudine (3TC) and Zidovudine (ZDV) in HIV-1 Infected Pregnant Women During Gestation and Post Partum, and in Their Infants Post Maternal Dosing

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Indinavir: antiretroviral, protease inhibitor

Purpose:

To see if indinavir, when combined with AZT and 3TC, is safe and well-tolerated in pregnant women and to see how these drugs are processed by womens' bodies. To determine what dose to give to the newborn infant.

About the study:

Participants will take indinavir (Crixivan), AZT and 3TC by mouth from the start of the study until 12 weeks after their babies are delivered. Women will come to the clinic every two weeks until week 36 of their pregnancy, then once a week until the start of labor. Mothers will have ultrasound performed between 18 and 20 weeks of pregnancy and every four weeks after week 26 of pregnancy. For three study visits, patients will come to the clinic before taking their morning dose of indinavir. One of these study visits will be about eight hours long. Mothers in active labor must **stop** taking indinavir and will receive their AZT by infusion into a vein. There are study visits at 6 and 12 weeks after giving birth. Newborn babies will take AZT and 3TC when they are taking liquids and will continue for six weeks. Babies will have study visits at 8 days, 3 weeks, 6 weeks, 3 months, and 6 months after birth.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- At least 13 years old
- Pregnant with a gestational age of at least 14 weeks to 28 weeks, based upon menstrual history and confirmed by ultrasound or sonograph
- Patients must be willing and able to drink six 8-ounce glasses of water a day

Not allowed:

- Prior treatment with any protease inhibitors
- Treatment with 3TC prior to pregnancy **or** more than three weeks treatment during this pregancy
- Treatment with any NNRTIs, such as delavirdine, nevirapine or Sustiva, within three weeks prior to study entry
- Current alcohol or substance abuse
- Active opportunistic infections
- Chronic malabsorption or diarrhea
- Chronic liver or kidney disease including kidney stones

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Maureen Shannon, FNP / CNM
(415) 206-8919

125. HIV Infection in Pregnant Women: Observational

Title:

Pediatric ACTG 367: Medical Chart Abstraction of HIV-Infected Pregnant Women and Their Infants Receiving Care or Consultation at Study Sites

Type of treatment:

Observational: none

Purpose:

To obtain general information and characteristics about HIV-infected pregnant women and their babies who have been (are being) seen at study sites. This information will be used to help design future studies for HIV-infected pregnant women.

About the study:

All information collected for this study will come from the mother's and the infant's medical chart. Some of the data to be collected includes information about prenatal care, laboratory tests relevant to HIV infection, medical history, obstetrical history, and use of anti-HIV medications during the pregnancy and the outcome of the pregnancy. All information collected is confidential and will not be linked to mother's and babies' names.

Required:

- HIV positive pregnant women
- Receiving care at a study site during the study period
- Infants born to study mothers

Not allowed:

- No exclusions

Location:

UCLA Medical Center - Pediatrics
Charmane Bernardo, RN
(310) 206-6369

126. HIV Infection in Pregnant Women: d4T, 3TC

Title:

Pediatric ACTG 332: A Phase I/II Open Label Study To Evaluate the Safety, Tolerance and Pharmacokinetics of Stavudine (d4T) in Combination with Lamivudine (3TC) in HIV Infected Pregnant Women and Their Infants

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how d4T is processed by women's bodies after the first trimester, through labor and delivery and to see how d4T is processed by their infants' bodies. To see what effect the combination of d4T and 3TC has on HIV viral load in pregnant women and their infants.

About the study:

Pregnant women in this study will take 3TC and d4T during pregnancy, labor and delivery. After delivery, infants will be divided into two groups: those whose mothers will allow them to receive AZT and those whose mothers will not allow them to receive AZT. Infants in Group 1 will receive AZT, 3TC and d4T; those in Group 2 will receive 3TC and d4T. AZT and 3TC are given to Group 1 babies by mouth for six weeks and d4T is given by mouth when the baby is 6 and 42 days old. Babies in Group 2 will receive d4T and 3TC by mouth every day for six weeks. Babies will be examined and have blood tests done eight weeks after medication is stopped and when they are six months old.

Required:

Mothers

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Intolerance of or refusal to take AZT
- Gestational age of 14-34 weeks by menstrual history or screening ultrasound

Infants

- Born to HIV-infected mothers who have received d4T/3TC as per study design

Not allowed:

Mothers

- Any acute infection within 14 days of study entry
- Severe peripheral neuropathy
- Uncontrollable diarrhea
- Current alcohol or substance abuse
- Mothers who plan to breastfeed their infants
- Use of antiretroviral or immunomodulatory medicines other than study drugs

Infants

- Infants who are unable to take medication by mouth or who have serious life-threatening illnesses

Location:

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

I27. HIV Infection in Women in Labor: AZT

Title:

Pediatric ACTG 324: A Phase I Trial of the Pharmacokinetics and Tolerance of Oral Zidovudine Administered to HIV-1 Infected Pregnant Women During Labor and Delivery

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see how AZT is processed by the body when taken by mouth in HIV-positive women during labor and delivery

About the study:

This study involves two groups of patients. At the onset of labor, the first group of patients will take three doses of AZT, three hours apart. Blood samples will be taken after each dose. After the last dose of AZT is taken by mouth, patients will take AZT by infusion into a vein until delivery of the baby. If no problems occur with the first group of patients, the second group will follow the same plan, except they will continue taking AZT by mouth after the third dose, rather than taking AZT by infusion into a vein. Patients will return to the clinic one week after delivery, and again four to eight weeks and six to eight months after delivery. Blood samples will be taken at each visit.

Required:

- CD4 cell (T-cell) range: not applicable
- Mothers must be HIV positive
- Mothers must be at least 34 weeks pregnant, confirmed by pelvic exam or ultrasound
- Prior treatment with AZT for at least 28 days during this current pregnancy

Not allowed:

- Use of any antiretroviral other than AZT
- Any active opportunistic or other serious infection at the time of study entry
- Intrauterine growth retardation
- Elective cesarean section
- Participation in any other perinatal treatment trial during this pregnancy

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

UCSF Pediatric Immunology Program
Maureen Shannon, FNP / CNM
(415) 206-8919

I28. HIV Exposure in Newborns: Cord Blood Bank

Title:

Pediatric ACTG 385: Establishment of a Cord Blood Bank for Gene Therapy in HIV-Infected Infants

Type of treatment:

Observational: none

Purpose:

To collect blood that is present in the umbilical cord of infants born to HIV-infected mothers. This blood will later be used in gene therapy testing if the infant is eligible.

About the study:

After delivery, blood will be collected from the umbilical cord and stored for possible use in a gene therapy study. Infants will have blood tests at one week and at 1, 2, 3 and 6 months of age to determine general health and HIV status. If the infant is found to be HIV infected, s/he will be eligible for gene therapy and the cord blood will be stored indefinitely. If the infant is uninfected at six months, there is an option to continue to have the cord blood stored at the study cord bank for up to four years or to have it stored at a bank of the mother's choice and at her expense. Infants will be in this study for six months.

Required:

- HIV positive women

Not allowed:

- Infants with congenital anomalies, as identified on ultrasound at birth

Location:

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSF Pediatric Immunology Program
Maureen Shannon, FNP / CNM
(415) 206-8919

129. HIV Infection in Newborns: Abacavir, AZT

Title:

Pediatric ACTG 321: Phase I Study of Safety, Tolerance, and Pharmacokinetics of 1592U89 with Standard Zidovudine (ZDV) Therapy in Neonates Born to HIV-1 Infected Mothers

Type of treatment:

AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Abacavir: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To find out the amount of abacavir (1592U89) there is in the blood of newborn babies who receive a single dose of abacavir in addition to AZT. To compare the safety of different doses of abacavir.

About the study:

This is a dose escalating study. This means that the first group of infants entering the study will receive the lowest dose of abacavir. If no bad side effects are seen, the next group of infants will receive a higher dose of abacavir. This study consists of two parts: Part 1 and Part 2. Part 1 has two groups: A and B. Group A is for infants 0 - 72 hours of age; Group B is for infants 21-28 days of age. Both groups will receive a single dose of abacavir and AZT on the first day. They will continue to take AZT four times a day for six weeks. Abacavir and AZT are taken by mouth. Five study visits are required for Part 1. Part 2 is a study of multiple doses of 1598U89 in infants 0-72 hours of age. All infants will take abacavir and AZT every day for six weeks. Six study visits are required. The study lasts eight weeks.

Required:

- CD4 cell (T-cell) range: not applicable
- Infants born to HIV-infected mothers
- Part 1A: Infants between birth and 72 hours old
- Part 1B: Infants between 21 and 28 days old

Not allowed:

- Infants with major congenital abnormalities
- Exposure (through the mother) to any protease inhibitors or NNRTIs
- Any serious infections requiring treatment during the study

Location:

UCLA Medical Center - Pediatrics
Maryanne Dillon, NP
(310) 206-6369

130. HIV Infection in Infants and Children: Ritonavir, AZT, 3TC

Title:

Pediatric ACTG 345: Phase I/II Study of Ritonavir in HIV-1 Infected Infants and Children

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Ritonavir: antiretroviral, protease inhibitor

Purpose:

To see if ritonavir is safe and well-tolerated when given in single and multiple oral doses, either alone or in combination with AZT and 3TC, to HIV-infected infants and children. Currently, no one knows exactly how much ritonavir should be given to infants and young children. This study, hopefully, will answer these important questions.

About the study:

The first children enrolled to the study will receive ritonavir by itself for seven days, then will be started on ritonavir, AZT and 3TC and be followed for the duration of the study. During the first seven days of the study, blood samples wil be drawn to measure the amount of ritonavir in the patient's blood. The results of these blood measurements will be used to adjust the amount of ritonavir given (either more or less) to the remaining children in the study. Study visits are every two weeks for the first month, then once a month for 17 months, then once every two months for an additional six months. Some study visits will have multiple blood draws. The study lasts about two years.

Required:

- HIV positive for children 3 months to 2 years old
- HIV exposed or presumed infected for infants less than 3 months old
- Between one month and two years of age

Not allowed:

- Any AIDS-defining opportunistic infection within two months of study entry
- Wasting or failure to thrive
- Any cancers
- Use of antiretrovirals for 6-12 weeks

Location:

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

131. HIV Infection in Infants: 3TC, d4T, Nevirapine, Nelfinavir

Title:

Pediatric ACTG 356: Early Intensive Antiretroviral Combination Therapy in HIV-1 Infected Infants and Children

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if the quadruple-drug therapy consisting of 3TC, d4T, nevirapine and nelfinavir is safe and effective in lowering the amount of HIV RNA in the blood to an undectectable amount. To see if these four drugs are safe when used in combination in HIV-infected infants.

About the study:

All patients will receive 3TC, d4T, nevirapine and nelfinavir; there are no placebos in this study. There are six study visits for blood tests during the first two weeks of the study. After the first two weeks, patients will have study visits once a month until week 24. Patients whose viral load is still measurable after 16 weeks will discontinue study medications and may be offered a different treatment. They will have study visits every three months for one year. Children whose viral load is not measurable after 16 weeks will remain on study medications through two years. Study vists for these children are once a month for three months, every two months for the rest of that year, then every three months for the second year of the study. The study lasts 104 weeks (2 years).

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive
- Between 15 days through three months old

Not allowed:

- More than six weeks of prior antiretroviral therapy, or any past infant use of nevirapine, or any mother who used nevirapine for more than two weeks
- Use of any other antiretrovirals, other investigational drugs, immunomodulators or HIV vaccines throughout the study
- Past clinical pancreatitis
- Infant or maternal use of more than one single dose of nelfinavir

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

132. HIV Infection in Infants: ALVAC HIV Vaccine

Title:

Pediatric ACTG 326: A Phase I/II Study to Evaluate the Safety and Immunogenicity of ALVAC HIV Vaccine Alone or with a Subunit Vaccine in Children Born to HIV-Infected Mothers

Type of treatment:

ALVAC Vaccine: vaccine

Purpose:

To see if canarypox HIV ALVAC vaccine is safe and effective in producing an immune response, when used alone or in combination with another vaccine, in infants born to HIV-infected mothers. To see how these vaccines affect the baby's immune system.

About the study:

HIV-infected mothers will be enrolled in this study when they are 37 weeks pregnant or as soon thereafter as possible. Newborn babies will be assigned by chance to receive either the ALVAC vaccine or placebo. Neither parents nor the baby's doctor will know which they are receiving until the study ends. The vaccine and its placebo are given by injection into the baby's thigh within 72 hours of birth and at 1, 2 and 3 months of age. The first two groups of babies will receive only the ALVAC vaccine or placebo. At a later date, when another vaccine product becomes available, another group of babies will be assigned by chance to receive either the ALVAC vaccine plus the new vaccine or placebo. Babies will have to stay in the clinic for one hour after each vaccine shot and return to the clinic 48 hours after each shot to be checked for problems. Study visits are every two weeks for the first 14 weeks of life, then every six months until the baby is two years old. There are a total of 12 study visits and the study lasts two years.

Required:

Mothers

- HIV positive
- At least 37 weeks pregnant

Infants

- Less than 72 hours old *May be receiving antiretroviral therapy

Not allowed:

Mothers

- Use of any investigational drug during pregnancy
- Use of passive or active immunotherapy during pregnancy
- Positive hepatitis B antigen at study entry

Infants

- Receipt of any investigational therapy
- Receipt of passive or active HIV-specific immunotherapy
- Documented or suspected serious bacterial infection or metabolic illness
- Infants being breastfed

Location:

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Maureen Shannon, FNP / CNM
(415) 206-8919

133. HIV Infection in Children: AZT, ddI, ddC, d4T, 3TC, Nevirapine, Ritonavir, Nelfinavir

Title:

Pediatric ACTG 366: A Phase I/II Master Protocol of Novel Antiretroviral Combination Therapies in Antiretroviral Experienced Children with Rapidly Progressing or Advanced HIV Disease (RAD)

Type of treatment:

3TC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
AZT: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
Nelfinavir: antiretroviral, protease inhibitor
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Ritonavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if certain drug combinations can decrease the amount of HIV in the blood and to see how long this decrease might last. To see if these combinations are safe to give to children with advanced HIV disease and to find the right doses of these drugs when used in various combinations.

About the study:

Patients will take one or two nucleoside analogs (such as AZT, ddI, ddC, d4T or 3TC). Depending on which drugs have previously been taken, children will also be assigned to take either 1) nevirapine plus nelfinavir or nevirapine plus ritonavir; 2) nevirapine plus nelfinavir plus ritonavir or 3) nelfinavir plus ritonavir. All study drugs are taken by mouth two or three times a day. Patients and doctors will know which medications they are taking and all medications are provided by the study. Study visits are once a month for the first six months, then every two months for the remainder of the study . The study lasts one year with the option to continue for an additional 48-week extension if children do well with their medications.

Required:

- Evidence of HIV infection
- Between 6 months and 21 years old
- Evidence of HIV disease progression or advanced disease while receiving at least eight weeks of unchanged continuous antiretroviral therapy
- Must be able to receive at least two drugs which patients have never used. One of these drugs must be ritonavir, nevirapine or nelfinavir

Not allowed:

- Acute treatment for a serious bacterial, viral or opportunistic infection within 14 days of study entry
- Cancers requiring chemotherapy
- Pregnant females
- Prior pancreatitis or severe peripheral neuropathy
- Prior use of ritonavir and nelfinavir in combination

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

134. HIV Infection in Children: CD4-IgG2

Title:

Pediatric ACTG 351: Phase I/II Trial of CD4-IgG2 in HIV-1 Infected Children

Type of treatment:

CD4-IgG2: viral blocker

Purpose:

To see if CD4-IgG2 is safe and to see what effect it has against the HIV virus in children. To see how CD4-IgG2 is processed by childrens' bodies.

About the study:

This study has two parts. Part 1 is a dose-escalating study. This means that the first group of children to enroll will receive the lowest dose of CD4-IgG2. If no bad side effects are seen, the next group of children will receive a higher dose and so forth until the fourth group of children get the higest dose of CD4-IgG2. CD4-IgG2 is given once by infusion into a vein. The infusion lasts about one hour and children will have to stay overnight in the hospital on the day they receive the infusion. There will be several blood draws on the day of the infusion. Study visits are on Days 1, 3, 7, 14 and 28 following the single infusion. There will be blood draws on these days. There will also be visits at 2, 3 and 4 months after the single infusion. Part 1 lasts four months. Children who enroll in Part 2 will receive infusions of CD4-IgG2 once a week for four weeks. The dose given will be established from Part 1. Children will have to stay overnight in the hospital each day the infusion is given. After the last infusion (week 3), blood will be drawn at 1, 2, 6, 24 hours, 7 days, and 14 days to see how much CD4-IgG2 is in the blood. Study visits will be at Weeks 7, 11, 15 and 19. Part 2 lasts five months.

Required:

- CD4 cell (T-cell) range:
  age 2-5 years: less than 500
  age 6-12 years: less than 200
- Viral load range (Part 2 **only**): at least 10,000 copies/mL
- HIV positive
- Between 2 and 12 years old
- Stable (no changes) antiretroviral therapy for at least three months prior to study entry

Not allowed:

- Active opportunistic infections
- Females who are pregnant
- Use of steroids or other immunosuppressive therapy
- Children receiving IVIG
- Children currently participating in a vaccine trial
- Any routine vaccination within 30 days of study entry

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

135. HIV Infection in Children: FTC

Title:

FTC-105: An Evaluation of the Safety and Pharmacokinetics of Single, Escalating Oral Doses of Emtricitabine (FTC) in HIV-1 Infected or Exposed Pediatric Patients Aged <18 Years Old

Type of treatment:

FTC: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see if two single escalating doses of FTC are safe and well-tolerated in HIV-infected or exposed pediatric patients from birth to late adolescence. To see how FTC is processed by pediatric patients. To find a dose of FTC in children that provides blood levels similar to that of adults.

About the study:

All eligible children will receive a single dose of FTC which is given as a strawberry-flavored solution and is swallowed. If no bad side effects are seen, a second larger dose of FTC will be given at least four days after the first dose. For each dose, blood samples will

be taken starting prior to drinking the dose and continuing up to 48 hours following each dose. For children over six years of age and who have tolerated the second dose of FTC, an additional capsule form dose of FTC may be given. Follow-up will be completed from four to seven days after the last dose of FTC has been given.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV positive or known exposure (born to HIV-infected mother)
- Under 18 years of age
- Children on antiretroviral therapy may continue that treatment with the exception of 3TC, which must be discontinued at least 24 hours prior to and 24 hours after each dose of FTC

Not allowed:

- No exclusions

Location:

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

I36. HIV Infection in Children: HAART and Immune Function

Title:

Pediatric ACTG P1006: The Effects of Highly Active Antiretroviral Therapy (HAART) on the Recovery of Immune Function in HIV-Infected Children

Type of treatment:

HAART: antiretrovirals, including at least one protease inhibitor

Purpose:

To see how many immune system cells return, how quickly those immune cells that are able to fight both new and old infections return, and the amount of HIV in the blood of children who are taking Highly Active Antiretroviral Therapy (HAART).

About the study:

Children who are about to begin taking HAART are eligible to join this study. After one month of taking HAART medications, children will be tested to see how much HIV is in their blood. If the amount of HIV in the blood has decreased by 10 times since the first test (screening), those children will continue in the study. If the amount of HIV has not decreased by 10 times since screening, those children will not continue in the study. Children continuing in the study will have study visits once a month until Week 48. Blood tests and physical exams will be done at each of these visits to determine the amount of HIV in the blood. During six of these visits, children will also be immunized. In total, children will receive three hepatitis A immunizations and three tetanus immunizations. After receiving all vaccines, children will come to the clinic three times the next year for follow-up at Weeks 52, 76 and 100. The study lasts about two years.

Required:

- CD4 cell (T-cell) range: less than 10%
- HIV positive
- Between 4 and 17 years old
- Must be starting HAART therapy of at least three drugs, two of which the child must have no prior experience (naive). One of the naive drugs must be a protease inhibitor or an NNRTI, such as Sustiva
- Children must have received three tetanus vaccines, with at least one vaccine within the past five years

Not allowed:

- Active opportunistic and/or bacterial infections
- Use of IVIG within six months of study entry and throughout the study
- Any cancers
- Females who are pregnant
- Children with immunity to hepatitis A
- Current use of hydroxyurea

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

137. HIV Infection in Children: Interleukin-2

Title:

Pediatric ACTG 299: Phase I/II Trial of Recombinant Interleukin-2 in Symptomatic Human Immunodeficiency Virus-Infected Children

Type of treatment:

Interleukin-2: immune modulator

Purpose:

To see if interleukin-2 is safe and effective for treating children who are HIV-infected. To find the highest dose of interleukin-2 that is safest for children to take.

About the study:

This is a dose escalating study. This means that the first children to enter the study will receive the lowest dose of interleukin-2. If this dose is tolerated with no bad side effects, the next group of patients will receive the next highest dose level and so forth until the highest dose that is tolerated with no bad side effects is found (Part A). Once the maximum tolerated dose has been determined, additional children will be enrolled to receive that dose (Part B). Interleukin-2 is given as an infusion into a vein. Children will receive a continuous infusion for five days in a row every eight weeks. This is called a cycle and children will complete three cycles. Those children who participated in Part A and did not receive the maximum tolerated dose of interleukin-2 will be eligible to participate in Part B to receive that dose. Parts A and B both last 44 weeks.

Required:

- CD4 cell (T-cell) range:
  age 3-5 years: 500 - 1000
  age 6-12 years: 200 - 500
- Viral load range: not applicable
- HIV positive
- Between 3 and 12 years old. Patients are eligible if they enter the study prior to their 13th birthday
- Patients must be receiving the best available antiretroviral therapy for at least one month and not more than 12 months prior to study entry
- Children must have symptomatic HIV infection

Not allowed:

- Any active opportunistic infection
- Any steroids or other immunosuppressive therapy
- Current polyclonal or monoclonal antibody therapy
- Current use of IVIG
- Females who are pregnant

Location:

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

138. HIV Infection in Children: Nelfinavir, Ritonavir, Nevirapine, d4T, ddI

Title:

Pediatric ACTG 403: PRAM-3: A Phase II Randomized, Multicenter Protocol Evaluating Two Antiretroviral Regimens Containing Combinations of Protease Inhibitors, NRTIs and an NNRTI

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
Nevirapine: antiretroviral, non-nucleoside reverse transcriptase inhibitor, NNRTI
Ritonavir: antiretroviral, protease inhibitor
d4T: antiretroviral, reverse transcriptase inhibitor, nucleoside analog
ddI: antiretroviral, reverse transcriptase inhibitor, nucleoside analog

Purpose:

To see which of two drug combinations does the best job of reducing the amount of HIV in the blood and to see how safe and well-tolerated they are in HIV-infected children. To see how these drugs are processed by childrens' bodies.

About the study:

Patients are assigned by chance to one of two groups. Children in Group 1 will take ddI, nelfinavir and ritonavir. Children in Group 2 will take d4T, nevirapine and nelfinavir. All medications are taken by mouth and children and parents will know which medications they are taking. Study visits are every two weeks for the first month, then once a month for the remainder of the study (for a total of 14 visits after study medications have been started). This study lasts 48 weeks.

Required:

- CD4 cell (T-cell) range:
  <12 months of age: at least 750
  1 - 5 years of age: at least 500
  6 years of age or older: at least 200
- Viral load range: at least 4,000 copies/mL
- HIV positive
- Between 4 months and 21 years old
- Must have been on continuous antiretroviral therapy for at least 16 weeks prior to study entry

Not allowed:

- Active opportunistic infections
- Prior use of any NNRTI, such as delavirdine, nevirapine or Sustiva
- Prior treatment with any protease inhibitor
- Past or current use of ddI
- Use of any investigational drug within 14 days of study entry
- Any cancers
- Females who are pregnant and/or breastfeeding

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
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UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

139. HIV Infection in Children: Sustiva (efavirenz), Nelfinavir

Title:

Pediatric ACTG 382: A Phase I/II, Open-Label, AUC-Controlled Study to Determine the Pharmacokinetics, Safety, Tolerability, and Antiviral Activity of DMP 266 in Combination with Nelfinavir in Children

Type of treatment:

Nelfinavir: antiretroviral, protease inhibitor
Sustiva: antiretroviral, non-nucleoside reverse transcriptase inhibitor (NNRTI)

Purpose:

To see if Sustiva (DMP 266) in combination with nelfinavir is safe and effective in treating HIV infection in children. To see which dose of nelfinavir is safest and best when combined with Sustiva. To compare the capsule form of Sustiva with the liquid form.

About the study:

Two groups of children will participate in this study. All children will take Sustiva and nelfinavir. Children in Group I will take Sustiva in capsule form. Children in Group II will take Sustiva in syrup form. The dose of each drug will be determined by the child's weight. Nelfinavir is either a powder or a tablet and taken by mouth. Children taking nelfinavir in powder form should mix it with milk or baby formula. Study visits are every two weeks for the first two months, then once a month. At Weeks 2, 6 and possibly 10, children will take their study drugs at the clinic and remain there for multiple blood tests throughout the day. The study lasts 48 weeks and children will have the option to continue Sustiva at the end of the study.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: detectable (more than 400 copies/mL)
- HIV positive
- Between 3 months and 2 years of age
- Must be taking one or more NRTI, such as AZT, ddI, ddC, 3TC or d4T

Not allowed:

- Prior use of any protease inhibitors or NNRTIs, such as delavirdine, nevirapine or efavirenz
- Use of any experimental drug within 30 days of study entry
- Hepatitis due to any cause
- Any cancer requiring systemic chemotherapy
- Active AIDS-defining opportunistic infections or disease
- Females who are pregnant
- More than two episodes of moderate to severe diarrhea or vomiting lasting more than four days within three months prior to study entry

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

140. HIV Infection in Children: T-20

Title:

Pediatric ACTG P1005: A Phase I/II Study of T-20, A Fusion Inhibitor, in HIV-1 Infected Children

Type of treatment:

T-20: antiretroviral, fusion inhibitor

Purpose:

T-20 is an experimental drug that works differently than other HIV medications. The purpose of this study is to see if T-20 is safe when given to children and to see how much T-20 gets into the blood when given by injection under the skin and through a vein. To see how well T-20 reduces the amount of HIV In the blood and to see how long it stays in the bloodstream.

About the study:

There are two parts to this study. In Part A, children will receive two injections of T-20; one under the skin and the other into a vein. The first group of children to enter the study will receive the lowest dose of T-20. If no bad side effects are seen, the next group of children will receive a higher dose. The first injection will be given under the skin and children must stay in the clinic for 12 hours for multiple blood tests (eight). After a physical exam, children in Part A will then receive the second injection of T-20

through a needle inserted into a vein. Again, children will remain in the clinic for 12 hours and have eight blood samples drawn. Part A will determine the dose of T-20 to be used in Part B. Children in Part B will have T-20 injections under the skin two times a day for 24 weeks along with prescribed antiretroviral medications. Parents and/or children will be taught how to give injections at home and how to dispose of needles safely. On Day 7, new antiretroviral medications will be prescribed. These medications are not provided by the study. There are six study visits in the first three weeks, then a visit every four weeks for a total of 12 visits. Some children may be allowed to continue taking T-20 for an additional 24 weeks depending on how well they respond to treatment. If children continue for 24 more weeks (to Week 48), there is a study visit once every two months for a total of three visits.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: more than 10,000 copies/mL on current therapy
- Must be on initial combination therapy for at least 16 weeks prior to study entry. Combination therapy is defined as two NRTIs alone or in combination with an NNRTI or a protease inhibitor
- HIV positive
- Between 3 and 12 years old

Not allowed:

- Acute opportunistic or bacterial infection requiring therapy at study entry
- Any cancers requiring chemotherapy
- Any child participating in Part A who experienced a bad side effect from T-20

Location:

Children's Hospital Los Angeles
Sarah Fox, RN
(323) 669-4537

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

141. Bacterial Infection Prevention in Children & Adolescents: Atovaquone, Azithromycin, TMP-SMX

Title:

Pediatric ACTG 254: A Randomized Study to Evaluate the Safety and Tolerance of Micronized-Atovaquone and Azithromycin (AT/AZ) as Compared to Trimethoprim-Sulfamethoxazole (TMP/SMX) in HIV Infected Children Aged 3 Months to 18 Months With HIV Infection

Type of treatment:

Atovaquone: antibacterial
Azithromycin: antibacterial
Trimethoprim-Sulfamethoxazole: antibacterial

Purpose:

To compare the combination of atovaquone and azithromycin with trimethoprim-sulfamethoxazole (TMP/SMX) to determine the long-term safety and tolerance of these different drugs. To observe any infections that may occur while taking these drugs.

About the study:

Patients are assigned by chance to receive atovaquone and azithromycin or TMP/SMX. All drugs are taken by mouth. Patients and their doctors will know which drugs they are taking. Children will take study drugs until they reach an age of 24 months. Clinic visits are every four weeks for the first four visits, then every eight weeks for two visits for a total of six visits.

Required:

- CD4 cell (T-cell) range: not specified
- Between 3 and 18 months of age
- HIV positive
- At risk for developing PCP

Not allowed:

- Active PCP
- Known intolerance to TMP/SMX
- Being treated for MAC, toxoplasmosis, tuberculosis, cryptosporidiosis or microsporidiosis
- More than three consecutive weeks use of atovaquone or azithromycin

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

142. Growth and Nutritional Status in Infants: Infant Formula

Title:

Pediatric ACTG 247: A Randomized, Double-Blind, Controlled Study of an Increased Caloric Density Infant Formula and its Effect on Growth and Nutritional Status in HIV-Infected Infants

Type of treatment:

Infant Formula:

Purpose:

To compare a higher calorie formula to a standard calorie formula and to see it's effect on improved growth in HIV-infected infants.

About the study:

Newborns of HIV-infected mothers are assigned by chance to receive a higher calorie formula or standard calorie formula. After eight weeks, infants with negative HIV-specific tests (presumed HIV-negative) will be assigned by chance to discontinue the study or to continue the study using the standard calorie formula. Those infants who are HIV positive will continue to take the formula to which they were assigned. Neither patients nor their doctors will know which formula they are taking until the study ends. All infants assigned to continue the study treatment beyond the eight week study visit will have study visits at Weeks 16, 28 and 52. At Week 28, study formula will be discontinued. Infants will start eating other foods when and as recommended by their doctors. The study lasts one year.

Required:

- CD4 cell (T-cell) range: not applicable
- HIV-infected mother
- Infants must be less than or equal to two weeks old
- Infants must weigh at least 4 pounds

Not allowed:

- Infants with congenital conditions that may result in a high probability that the infant will not survive beyond the 28-week treatment period
- Infants taking drugs that alter growth such as Megace, corticosteroids or growth hormone
- Any metabolic disorder resulting in malabsorption
- Women who decide to breastfeed their infants

Location:

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCLA Medical Center - Pediatrics
Charmane Bernardo, RN
(310) 206-6369

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

143. HIV Infection in Children: Varicella-Zoster Virus Vaccine

Title:

Pediatric ACTG 391: Use of Live-Attenuated Varicella-Zoster Virus (VZV) Vaccine To Boost Immunity to VZV in HIV-Infected Children Previously Infected with Varicella

Type of treatment:

Varicella Vaccine: vaccine

Purpose:

To see if Varicella Virus Vaccine (Varivax) is safe and if it can help to prevent shingles in HIV-infected children who have already had chicken pox.

About the study:

Eligible children will be given the chickenpox vaccine by injection under the skin. Patients must remain in the clinic for an hour after the injection for observation. Study visits are at Weeks 4, 8, 12, 24, 36, 52 and 78 after the first injection was given at study entry. Study visits will include blood tests, medical history updates and physical exams. Patients who tolerated the first vaccine at study entry will be given a second dose on the 8th week visit. All patients will have a final study visit at Week 104. The study lasts two years.

Required:

- CD4 cell (T-cell) range: at least 10% for at least six months prior to chickenpox and between 10 and 15% for at least six months prior to enrollment
- HIV positive
- Between 2 and 18 years old
- Stable (no changes) antiretroviral treatment for at least three months prior to study entry
- Positive varicella zoster antibody test
- Past chickenpox for at least six months prior to study entry and at least one year old

Not allowed:

- Any active infections within 72 hours of study entry
- Fever over 101 F within 72 hours of study entry
- Chickenpox exposure and/or exposure to herpes zoster (shingles) within four weeks of study entry
- Past episode of herpes zoster (shingles)
- Use of steroids or any other immunosuppressive treatment within 30 days of study entry
- Use of a live vaccine within 30 days or use of an inactive vaccine within two weeks prior to study entry
- Prior use of varicella vaccine
- Current use of aspirin or expected use within six weeks after a study immunization
- Females who are pregnant
- Use of IVIG or any blood products within one year of study entry
- Treatment with any anti-herpes drug (such as acyclovir, famciclovir, valacyclovir, cidofovir, ganciclovir, interferons or foscarnet) within one week prior to a study immunization

Location:

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

144. HIV Infection in Adolescents: Observational

Title:

Pediatric ACTG 381: Establishment and Maintenance of Long-Term Undetectable Plasma HIV-1 RNA: Correlation with Immunologic Reconstitution and Viral Dynamics

Type of treatment:

Observational: none

Purpose:

To find out if those adolescents with better immune systems before starting Highly Active Antiretroviral Therapy (HAART) do better than those who have weaker immune systems before starting HAART.

About the study:

After screening, eligible patients are asked to participate in an education and counseling session before starting HAART. There will be two videos, audio tapes, take-home reading materials and a question-answer period. The HAART medications will be determined by the patient's doctor and should be obtained through prescription. No medications will be provided by this study. Within 72 hours after starting HAART, patients must return to the clinic for blood tests and skin test. The skin test is done by an injection just underneath the skin surface. There are three study visits the first week and two visits the second week. Patients will then return for a study visit during each of the following weeks: Weeks 4, 8, 12, 16 and 24. After Week 24, visits are every three months until the end of the study. Patients will be in this study for at least three years.

Required:

- CD4 cell (T-cell) range: not applicable
- Viral load range: must be detectable
- At least 8 years old up to and including the 22nd birthday

Not allowed:

- Any use of HAART or combination therapy
- HIV infection through perinatal transmission
- Use of immunotherapy, HIV vaccines, HIVIG or cytokine therapy
- Known to have acquired infection by transfusion during the perinatal period

Location:

Children's Hospital Los Angeles
Sarah Fox, RN
(323) 669-4537

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

145. HIV Infection in Children and Adolescents: Observational

Title:

Pediatric ACTG 219: Pediatrics Late Outcomes Protocol

Type of treatment:

Observational: none

Purpose:

To learn about the long-term survival and quality of life of infants and children enrolled in ACTG studies. To learn more about the differences between HIV disease progression in HIV+ infants and children, and the effects of anti-HIV drugs in infants and children who are not HIV+.

About the study:

All patients get physical exams and blood tests on a regular basis. Information on health problems and quality of life are also collected. Patients will be in the study until their 21st birthday.

Required:

- CD4 cell (T-cell) range: not specified
- An infant, child or adolescent born to an HIV^+ woman who was enrolled in an ACTG study while pregnant, or
- HIV^+ infant or child ever enrolled in an ACTG treatment study

Not allowed:

- Children enrolled only in ACTG 220 or other observational studies

Location:

Bay Area Perinatal AIDS Center (BAPAC)
Maureen Shannon, FNP / CNM
(415) 206-8919

Children's Hospital Los Angeles
Sarah Fox, RN
(323) 669-4537

Children's Hospital, Oakland
Teresa Courville, RN, MN
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LAC-USC Medical Center
Maternal Child Program
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UCLA Medical Center - Pediatrics
Charmane Bernardo, RN
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146. HIV Infection in Children: Observational

Title:

Pediatric ACTG P1008: An Observational Study of the Rate of Opportunistic Infection Events in HIV-Infected Children Who Have Demonstrated Immunologic Reconstitution and Who Have Discontinued OI Prophylaxis

Type of treatment:

Observational: none

Purpose:

To see if it is safe to stop giving medicines to prevent PCP, MAC and other infections for those children who are responding well to their antiretroviral treatment.

About the study:

Children who have agreed to stop taking medications for the prevention of infections will be enrolled in this study. During the first visit, children will receive the first of two doses of Hepatitis A vaccine. The response to this vaccination will help the doctors find out if the immune system is working well and may also help the doctors predict if children are at risk for developing new infections once preventive medications have been stopped. Study visits are every eight weeks for at least two years (at least 13 visits). At these visits, physical exams will be performed as well as blood samples taken. At Week 24, children will receive the second dose of Hepatitis A vaccine. This study lasts at least two years.

Required:

- CD4 cell (T-cell) range:
  age 2 to <6: at least 25%
  age 6-21: at least 20%
- HIV positive
- Age 2 years up to and including the 21st birthday
- Must have been receiving PCP preventive medications for at least six months, and for at least three months prior to study entry
- Must have received continuous antiretroviral therapy or at least 16 weeks prior to study entry
- Willingness to discontinue PCP and MAC preventive medications

Not allowed:

- Suspected or proven active PCP
- Active infections such as toxoplasmosis, tuberculosis, cryptosporidia and microsporidia requiring treatment at the time of study entry
- Any cancers requiring chemotherapy
- Children requiring systemic antimicrobial or antifungal preventive medications other than standard PCP prophylaxis

Location:

Children's Hospital Los Angeles
Sarah Fox, RN
(323) 669-4537

Children's Hospital, Oakland
Teresa Courville, RN, MN
(510) 428-3885, ext. 2827

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSD Mother, Child and Adolescent HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

147. Mononuclear Cell Phenotyping in Normal Children: Observational

Title:

Pediatric ACTG P1009: Mononuclear Cell Phenotyping in Normal Children

Type of treatment:

Observational: none

Purpose:

To learn more about some of the cells in the blood of healthy children. Researchers hope that by learning more about the blood cells of healthy children they can better understand the differences in the blood cells of children infected with HIV

About the study:

This study lasts for one visit. During this visit, questions will asked about the child's medical history, age, race and ethnicity. One blood sample will be taken at this visit.

Required:

- HIV negative
- Patients up to their 19th birthday may be enrolled (age 0-18)

Not allowed:

- HIV infection or perinatal exposure
- Females who are pregnant
- Acute infectious illness, clinically significant diseases or chronic viral infections
- Prescription medications other than vitamins

Location:

LAC-USC Medical Center
Maternal Child Program
Eva Operskalski, Ph.D., MBA
(323) 226-2342

UCSD Mother, Child and Adolescent
HIV Program
Myrene Preston
(619) 543-8080 ext. 204

UCSF Pediatric Immunology Program
Deborah Trevithick, RN, MS
(415) 476-6480

Compassionate Use, Expanded Access and Treatment IND Programs

Any new drug must be approved by the Food and Drug Administration (FDA) before it can be prescribed by a physician. FDA approval is based on the results of clinical trials. Many months or even years of clinical trials and analysis of the results may be needed before approval can be granted. Such a long testing period is necessary in order to learn about the safety and effectiveness of the drug. But sometimes, even during fairly early phases of testing, a drug may appear to have benefits which outweigh the risks of taking it before it has been fully tested. This is especially true when people cannot take any of the approved drugs, when approved drugs do not work, or for conditions which have previously been untreatable. Compassionate Use, Expanded Access and Treatment IND are programs which allow patients limited access to promising experimental treatments before they have been given full approval by the FDA. They are developed jointly by the FDA and the pharmaceutical company that makes the drug.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
ddC (zalcitabine, HIVID)	HIV Infection (pediatric)	Hoffmann-LaRoche Open Label Program	800-285-4484
Lopinavir (ABT-378/Ritonavir)	HIV Infection	Abbott Laboratories Expanded Access Program	888-711-7193
Nitazoxanide (NTZ)	*Cryptosporidium*	Romark Labs Compassionate Use Protocol	813-282-8544
Spiramycin	Chronic diarrhea caused by *Cryptosporidium*	Rhone-Poulenc Rorer Compassionate Use Protocol	800-727-6737
Tenofovir disoproxil (bis-POC PMPA)	HIV Infection CD4 count <50	Gilead Sciences Expanded Access	800-276-0231

California AIDS Drug Assistance Program

The California AIDS Drug Assistance Program (ADAP) was established to provide drugs to individuals who otherwise could not afford them. Individuals are eligible for ADAP if they (1) have a **federal** adjusted gross income below $50,000 per year, (2) have a valid prescription from a California-licensed physician, and (3) the drugs they need are not covered by Medi-Cal or other third-party payer. An individual is subject to a co-payment if his/her annual **federal** adjusted gross income is between 400% of poverty level and $50,000. Individuals with an annual gross income below 400% of poverty level receive the drugs free of charge.

For more information about ADAP call the California Office of AIDS at **916-327-6784**. County and local offices in California are listed on the next page. Other States have similar programs. To find the ADAP pharmacy nearest to your location, please call PMDC at (888) 575-2327.

California AIDS Drug Assistance Program - Covered Drugs

Drug Names	Used for
Acyclovir, Zovirax	antiviral, herpes treatment
Agenerase, Amprenavir	antiretroviral, protease inhibitor
Albendazole, Albenza	microsporidiosis
Amitriptyline, generic only	antidepressant
Amphotericin B, Fungizone	fungal infections
Amoxicillin, generic only	antibiotic
Atorvastatin, Lipitor	lipid-lowering agent
Atovaquone, Mepron	antibacterial, PCP treatment
Azithromycin, Zithromax	antibacterial, MAC infections
Bleomycin sulfate, Blenoxane	antineoplastic, chemotherapy
Bupropion, Wellbutrin (short-acting only)	antidepressant
Cephalexin, oral generic only	antibiotic
Cidofovir, Vistide	antiviral, CMV disease
Clarithromycin, Biaxin	antibacterial, MAC infections
Clindamycin, Cleocin	antibacterial, PCP/Toxoplasmosis
Clofazimine, Lamprene	antimycobacterial, MAC infections
Clotrimazole, Mycelex, Lotrimin	antifungal, candidiasis
Codeine phosphate, oral generic only	analgesic
Codeine phosphate/aspirin, oral generic only	analgesic
Codeine sulfate, oral generic only	analgesic
Cyclophosphamide, Cytoxan	antineoplastic, chemotherapy
Dapsone,, Avlosulfon	antibacterial, PCP treatment
Daunorubicin, liposomal, DaunoXome	antineoplastic, KS treatment
Delavirdine, Rescriptor	antiretroviral, NNRTI
Desipramine, generic only	antidepressant
Dexamethasone, Decadron, Hexadrol	corticosteroid
Dicloxacillin, oral generic only	antibiotic
Didanosine, ddI, Videx	antiretroviral, nucleoside analog
Diphenoxylate, Lomotil	antidiarrheal
Doxorubicin, Adriamycin	antineoplastic, chemotherapy
Doxycycline, oral generic only	antibiotic
Dronabinol, Marinol	appetite stimulant, wasting syndrome
Erythromycin ethylsuccinate, oral generic only	antibiotic
Erythropoietin, EPO, epoetin alpha, Procrit	red blood cell stimulator
Ethambutol, Myambutol	antimycobacterial, MAC infections
Fenoprofen calcium, oral generic only	analgesic
*Fentanyl, Duragesic	analgesic
Filgrastim, Neupogen, G-CSF	white blood cell stimulator
Fluconazole, Diflucan	antifungal, candidiasis/cryptococcus
Flucytosine, 5FC, Ancobon	antifungal, candidiasis/cryptococcus
Fluoxetine, Prozac	antidepressant

California AIDS Drug Assistance Program - Covered Drugs

Drug Names	Used for
Foscarnet, Foscavir	antiviral, CMV disease
Ganciclovir, IV, Cytovene, Implant	antiviral, CMV disease
Gemfibrozil, Lopid	lipid-lowering agent
Hepatitis B vaccine, Recombivax HR, Energix-B	vaccine
Hydrocodone, oral generic only	analgesic
Hydroxyurea, Hydrea, Droxia	HIV Host Factor Inhibitor, chemotherapy
Ibuprofen, oral generic only	analgesic
Ibuprofen/hydrocodone, oral generic only	analgesic
Indinavir, Crixivan	antiretroviral, protease inhibitor
Indomethacin, oral generic only	analgesic
Interferon, alpha, Intron-A, Roferon-A	KS treatment
Itraconazole, Sporanox	antifungal
Ketoconazole, Nizoral	antifungal, candidiasis
Ketoprofen, oral generic only	analgesic
Lamivudine, 3TC, Epivir	antiretroviral, nucleoside analog
Lamivudine/Zidovudine, Combivir	antiretroviral, nucleoside analog
Leucovorin, Wellcovorin, Folinic acid	white blood cell protector, PCP treatment
Levorphenol, oral generic only	analgesic
Loperamide, Imodium	antidiarrheal
Megestrol acetate, Megace	appetite stimulant, wasting syndrome
Methadone, oral generic only	analgesic
Methotrexate, MTX, Reumatrex	antineoplastic, chemotherapy
Metronidazole, oral generic only	amoebiasis
Minocycline, oral generic only	antibiotic
Morphine sulfate, oral generic only	analgesic
Naproxen, oral generic only	analgesic
*Nandrolone decanoate, Deca-Durabolin	anabolic steroid, wasting syndrome
*Nandrolone phenpropionate, Durabolin	anabolic steroid, wasting syndrome
Nefazodone, Serzone	antidepressant
Nelfinavir, Viracept	antiretroviral, protease inhibitor
Neomycin sulfate, oral generic only	antibiotic
Nevirapine, Viramune	antiretroviral, NNRTI
Nortriptyline, oral generic only	antidepressant
Nystatin, Mycostatin	antifungal, candidiasis
Opium, tincture of, Laudanum	anidiarrheal
*Oxandrolone, Oxandrin	anabolic steroid, wasting syndrome
Oxycodone, oral generic only	anal;gesic
Paclitaxel, Taxol	antineoplastic, KS treatment
Paromomycin, Humatin	antiparasitic, Amoebiasis/Cryptosporidiosis
Paroxetine, Paxil	antidepressant
Penicillin V potassium, oral generic only	antibiotic
Pentamidine, aerosolized, Nebupent, Pentaire, Aeropent	antiparasitic, PCP treatment
Pneumococcal vaccine, Pneumovax, Pnu-Imune	vaccine
Pravastatin, Pravachol	lipid-lowering agent
Prednisone, Deltasone, Meticorten, Orasone	steroid, anti-inflamatory
Pyrimethamine, Daraprim	antibacterial, toxoplasmosis
Rifabutin, Mycobutin	antimycobacterial, MAC infections
Ritonavir, Norvir	antiretroviral, protease inhibitor
Saquinavir, Fortovase, Invirase	antiretroviral, protease inhibitor
Serostim, somatropin	human growth hormone, wasting syndrome
Sertraline, Zoloft	antidepressant
Simvastatin, Zocor	lipid-lowering agent
Stavudine, d4T, Zerit	antiretroviral, nucleoside analog
Sulfadiazine, Microsulfon	antibacterial, toxoplasmosis
Sulindac, oral generic only	analgesic
Sustiva, efavirenz, DMP 266	antiretroviral, NNRTI

California AIDS Drug Assistance Program - Covered Drugs

Drug Names	Used for
*Testosterone cypionate, Depotest, Duratest	anabolic steroid, wasting syndrome
*Testosterone enanthate, Andro LA, Delastryl	anabolic steroid, wasting syndrome
*Testosterone porpionate, generic only	anabolic steroid, wasting syndrome
Tetracycline, oral generic only	antibiotic
Trazadone, generic only	antidepressant
Trimethoprim, Trimpex, Proloprim	antibacterial, PCP treatment
Trimethoprim-Sulfamethoxazole, Bactrim, TMP-SMX, Septra	antibacterial, PCP treatment
Trimetrexate glucuronate, NeuTrexin	antibacterial, PCP treatment
Valacyclovir, Valtrex	antiviral, herpes treatment
Vancomycin, oral generic only	antibiotic
Venlafaxine, Effexor	antidepressant
Vinblastine, Velban	antineoplastic, chemotherapy
Vincristine, Oncovin, Vincasar	antineoplastic, chemotherapy
Zalcitabine, ddC, HIVID	antiretroviral, nucleoside analog
Ziagen, Abacavir, 1592U89	antiretroviral, nucleoside aanalog
Zidovudine, AZT, ZDV, Retrovir	antiretroviral, nucleoside analog

* Restricted

County and Local Contacts for AIDS Drug Assistance Program in California

Alameda County Health Dept.
(510) 667-3937

Amador County
(209) 736-6792

City of Berkeley
(510) 644-6355

Butte County
(530) 891-4226

Calaveras County
(209) 736-6792

Colusa County
(530) 742-0891

Contra Costa County
Bud Getty
(925) 313-6602

Del Norte County
(707) 464-3191

El Dorado County
(530) 573-3160

Fresno County
(209) 445-3434

Glenn County
(530) 934-6588

Humboldt County
(707) 268-2184

Imperial County
(760) 339-4448

Inyo County
(760) 872-4246

Kern County
(805) 861-0491

Kings County
(209) 584-1401, x4520

Lake County
(707) 263-2241

Lassen County
(530) 251-8183

Long Beach
Rosie Gutierrez
(562) 570-4316

Los Angeles County
(213) 351-8100

Madera County
(559) 675-7627

Marin County
(415) 499-3624

Mendocino County
(707) 463-4573

Merced County
(209) 385-7709

Modoc County
(530) 529-4400

Mono County
(760) 924-5415

Monterey County
(408) 772-7208

Napa County
(707) 253-4570

Nevada County
(916) 477-5551

Orange County
(714) 834-8175 or
(714) 834-8241

City of Pasadena
(626) 744-6029

Placer County
(530) 889-7144

Plumas County
(530) 283-6357

Riverside County
(909) 486-4626

Sacramento County
(916) 874-9583

San Benito County
(408) 636-4066

San Bernardino County
(909) 383-3036 or
(909) 386-8112

San Diego County
(619) 692-5545

San Joaquin County
(209) 468-3891

San Luis Obispo County
(805) 781-3660

San Mateo County
(650) 573-2032

Santa Barbara County
(805) 681-4758

Santa Clara County
(408) 299-6150

Santa Cruz County - Medi-Cruz Program
(408) 454-4568

Shasta County
(916) 247-3338

Sierra County
(530) 993-6705

Siskiyou County
(530) 842-7345

Solano County
(707) 553-5124

Sonoma County
(707) 524-7402

Stanislaus County
(209) 558-4800

Sutter County
(530) 742-0891

Tehama County
see Shasta

Trinity County
see Shasta

Tulare County
(209) 685-2535

County and Local Contacts for AIDS Drug Assistance Program in California

Tuolumne County
(209) 533-7400, x7412

Ventura County
(805) 652-5780

Yolo County
(916) 666-8673

Yuba County
(530) 742-0891

NOTE: The following counties do not provide ADAP services at the local level:

Alpine Mariposa

Please call the state Office of AIDS, ADAP
see page 91

Patient Assistance Programs

Some pharmaceutical companies have programs that provide free or lower cost medications to patients who could not otherwise pay for them. Each program has specific requirements about who is eligible and what kind of financial help is available. If you need help paying for any of the drugs listed below, talk to your doctor. He or she will need to call the coordinators of the appropriate program(s) and give them information about your financial status and prescription drug needs.

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Amplicor Viral Load Testing	HIV Viral Load	Roche Diagnostics	888-837-8727
Chiron bDNA Viral Load Testing	HIV Viral Load	Chiron Laboratories	800-775-7533
3TC (Lamivudine, Epivir)	HIV Infection	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Abacavir (Ziagen, 1592U89)	HIV Infection	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Acyclovir (Zovirax)	Herpes simplex, Herpes zoster	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Agenerase (amprenavir)	HIV Infection	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Albenza (albendazole)	Microsporidiosis	Smith-Kline Beecham	800-546-0420
Alpha Interferon-2A recombinant (Roferon-A)	Kaposi's Sarcoma (>200 T-cells) anogenital neoplasms	Hoffmann-LaRoche, Inc. Oncoline (Reimbursement assistance and literature search) Indigent Patient Program	 800-443-6676 800-285-4484
Alpha Interferon-2B recombinant (Intron A)	Kaposi's Sarcoma anogenital neoplasms	Schering-Plough Corp. Commitment to Care	800-521-7157
AmBisome (Liposomal Amphotericin B)	Fungal Infections	Fujisawa USA, Inc.	800-477-6472
Amphotericin B Lipid Complex (ABELCET)	Life threatening fungal infections	Liposome Co. Indigent Patient Program	 800-335-5476
Amphotericin B oral suspension (Fungizone)	Fungal Infections	Bristol-Myers Squibb	800-272-4878
Atovaquone (Mepron)	PCP treatment	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
AZT (zidovudine, Retrovir)	HIV Infection	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Azithromycin (Zithromax)	Toxoplasmosis, MAC	Pfizer Inc. Premiere Research	800-869-9979
Bleomycin (Blenoxane)	Chemotherapy	Bristol-Myers Squibb	800-272-4878
Cidofovir (Vistide)	CMV Retinitis	Gilead Sciences	800-445-3235
Cimetidine (Tagamet)	Ulcers	SmithKline Beecham, Access To Care	800-546-0420

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Ciprofloxacin (Cipro)	Bacterial Infections	Bayer Indigent Patient Program	800-998-9180
Clarithromycin (Biaxin)	MAC	Abbott Laboratories Physician calls only	800-688-9118
Clindamycin (Cleocin)	PCP treatment	Pharmacia Upjohn Patient Assistance Program	800-242-7014
Clofazimine (Lamprene)	MAC Treatment/Prevention	Novartis Pharmaceuticals Patient Assistance	800-257-3273
Combivir (AZT/3TC Fixed Dose)	HIV Infection	Glaxo Wellcome Co. HIV Patients Assistance Program	800-513-3028
Compazine (Prochlorperazine)	Nausea	SmithKline Beecham Access To Care	800-546-0420
Crixivan (Indinavir)	HIV Infection	Merck Pharmaceuticals	800-850-3430
DaunoXome (liposomal daunorubicin)	KS	NeXstar Pharmaceuticals DaunoXome Hotline	800-226-2056
Delavirdine (Rescriptor)	HIV Infection	Pharmacia-Upjohn Rescriptor Hotline	800-711-0807
ddC (zalcitabine, HIVID)	HIV Infection	Hoffman-La Roche Patient Assistance Program	800-282-7780
ddI (didanosine, Videx)	HIV Infection	Bristol-Myers Squibb Patient Assistance Program	800-272-4878
d4T (stavudine, Zerit)	HIV Infection	Bristol-Myers Squibb Patient Assistance Program	800-272-4878
DOXIL (doxorubicin, liposomal)	Kaposi's Sarcoma	SEQUUS Pharmaceuticals Patient Assistance Program	800-375-1658
Dronabinol (Marinol)	Appetite Stimulant	Roxane Laboratories Patient Assistance Program	800-274-8651
EPO (erythropoietin, Procrit)	AZT-related Anemia	Ortho Biotech Procrit Financial Assistance Program	800-553-3851
Ethambutol (Myambutol)	TB Treatment, MAC Treatment	Wyeth-Ayerst Lederle Labs Physician Calls Only	800-568-9938
Fluconazole (Diflucan)	Fungal Infections	Pfizer Inc. Diflucan Patient Assistance program	800-869-9979
Foscarnet (Foscavir)	CMV Disease, Acyclovir-resistant HSV	Astra Pharmaceuticals Foscavir Assistance	800-488-3247
Fortovase (saquinavir)	HIV Infection	Hoffman-LaRoche Patient Assistance Program	800-282-7780
Ganciclovir (Cytovene)	CMV Disease	Hoffman-LaRoche Patient Assistance Program	800-282-7780
Ganciclovir (oral)	CMV Retinitis	Hoffman-LaRoche Patient Assistance Program	800-282-7780
Ganciclovir implant (Vitrasert)	CMV Retinitis	Chiron Vision Vitrasert Reimbursement Hotline	800-338-2020
G-CSF (Neupogen)	AZT-related Neutropenia	Amgen, Inc.	800-272-9376

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
GM-CSF (Leukine)	AZT-related Neutropenia	Immunex Corporation (Physician calls only)	800-334-627
Hydroxyurea (Hydrea)	HIV Infection	Bristol-Myers Squibb	800-272-4878
Invirase (saquinavir)	HIV Infection	Hoffman-LaRoche, Inc. Patient Assistance Program	800-282-7780
Itraconazole (Sporanox)	Histoplasmosis, Fungal Infections	Janssen Pharmaceutica Patient Assistance Program	800-652-6227
Ketoconazole (Nizoral)	Fungal Infections	Janssen Pharmaceutica Patient Assistance Program	800-652-6227
Megestrol Acetate (Megace)	HIV-related Wasting	Bristol-Myers Squibb Patient Assistance Program	800-272-4878
Methotrexate (Rheumatrex)	Chemotherapy	Wyeth Ayerst Lederle Labs Physician Calls Only	800-568-9938
Mexiletine (Mexitil)	Peripheral Neuropathy	Boehringer Ingelheim	800-556-8317
Morphine Sulfate (Roxanol)	Pain Management	Roxane Laboratories	800-274-8651
Mycelex (Clotrimazole)	Oral Candidiasis (thrush)	Bayer Indigent Patient Program	800-998-9180
Nelfinavir (Viracept)	HIV Infection	Agouron Pharmaceuticals	888-777-6637
Nevirapine (Viramune)	HIV Infection	Roxane Laboratories Patient Assistance Program	800-274-8651
Nystatin (Mycostatin)	Oral Candidiasis (thrush)	Bristol-Myers Squibb	800-272-4878
Octreotide Acetate (Sandostatin)	Wasting	Novartis Indigent Patient Program	800-257-3273
Oxandrolone (Oxandrin)	Wasting	BTG Pharmaceuticals	800-741-2698
Paclitaxel (Taxol)	KS Chemotherapy	Bristol-Myers Squibb	800-272-4878
Paromomycin (Humatin)	Cryptosporidiosis	Parke-Davis Patient Asistance	908-725-1247
Pentamidine (Nebupent)	PCP Prophylaxis	Fujisawa, USA, Inc.	800-477-6472
Pentoxifylline (Trental)	HIV Infection, KS, Dementia	Hoechst Marion Roussel Inc. Indigent Patient Program	800-552-3656
Phenytoin (Dilantin)	Seizure Disorder	Parke-Davis Patient Assistance	908-725-1247
Pyrimethamine (Daraprim)	Toxoplasmosis	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Pyrazinamide (USP)	TB Treatment	Wyeth Ayerst Lederle Labs Physician Calls Only	800-568-9938
Rifabutin (Mycobutin)	MAC	Pharmacia Upjohn Inc.	800-242-7014

Patient Assistance Programs

Name of Drug	What Drug is Used For	Company and Name of Program	Telephone
Ritonavir (Norvir)	HIV Infection	Abbott Laboratories Physician calls only	800-688-9118
Serostim (Growth Hormone)	HIV Wasting Syndrome	Serono Laboratories	800-714-2437
Sparfloxacin (Cinarcid, Zagam)	Respiratory Infections	Rhone-Poulenc Rorer	800-727-6737
Streptomycin	TB Treatment	Pfizer, Inc. Patient Assistance Program	800-254-4445
Sustiva (efavirenz, DMP 266)	HIV Infection	DuPont Pharmaceuticals	800-334-4486
Testosterone (Testoderm patch)	Wasting	Alza Pharmaceuticals	800-321-3130 ext. 2287
Thalidomide (Thalomid)	Wasting, Aphthous Ulcers	Celgene Corporation	888-423-5436
TMP/SMX (Septra)	PCP Prophylaxis and Treatment	Glaxo-Wellcome HIV Patient Assistance Program	800-513-3028
TMP/SMX (Bactrim)	PCP Prophylaxis and Treatment	Hoffman-La Roche Inc., Patient Assistance	800-282-7780
Trimetrexate (Neutrexin)	PCP Treatment	US Bioscience Patient Assistance	800-887-2467
Valacyclovir (Valtrex)	Herpes Treatment	Glaxo Wellcome Co. HIV Patient Assistance Program	800-513-3028
Vinblastine (Velban)	Chemotherapy	Eli Lilly Cares	800-545-6962
Vincristine (Oncovin)	Chemotherapy	Eli Lilly Cares	800-545-6962
Vitravene (fomivirsen, ISIS 2922)	CMV Retinitis	CIBA Vision Reimbursement Services	877-458-9393
WinRho SD	Thrombocytopenia	Nabi Reimbursement Service	800-789-2099

Common Questions about Clinical Trials

What is a clinical trial?

A new drug goes through many tests in the lab before people take it. If the results are good, the drug is tested in small groups of people. When people take a new drug as part of a study, it is called a clinical trial.

The results of a clinical trial are very important. They tell us about the safety of the drug when people take it. They also tell us if the drug helps people get better.

Why should I join? What do I get out of this?

Here are some of the reasons to join a clinical trial:

- The treatment being tested may work for you.
- Clinical trials may be the only way to get a promising new drug.
- Drugs taken as part of a clinical trial are usually free. (Even if a drug you want to take is available on the "under ground," or by prescription, you may not be able to afford it).
- You can help speed the development of new treatments for HIV.

Will I be used as a "guinea pig"?

Before you join a clinical trial, you should understand what will happen during the study and what the researchers hope to learn. When you join a clinical trial, you volunteer of your own free will. Even though you signed a consent form, you have the right to quit at any time.

In most cases, you join a clinical trial because you already have a disease and you think the drug being tested may help you. Sometimes, you may join a clinical trial while you are still healthy, in the hope that the treatment may prevent you from getting sick.

What if the drug makes me sicker?

The researchers who design the trials always plan what to do if a volunteer gets ill from the drug they are studying. If the drug makes you sicker, you may have to take a lower dose, or stop taking the drug completely. In some trials, you might be switched to another drug. You should keep in close contact with your doctor as well as the researchers so they can treat any side effects as soon as possible.

Will I have to take a placebo ("sugar pill")?

Placebos are usually used only when no effective treatment is known. In these cases a "placebo-controlled" study is the only reliable way to find out if a drug works. Some patients are asked to take placebos so researchers can learn whether changes in health are caused by the drug, or would have happened without treatment.

Patients who take placebos get the same medical attention as people who get the study drug. Usually, all patients in the study are offered the active drug if it is shown to be safe and effective.

How can I tell which trial might be good for me?

The more you know about your own health status and about HIV disease, the easier it will be for you to make decisions about what trials may be good for you. You should always talk to your doctor or health care provider to get their opinions, too. We list contact names and numbers for the trials included in this directory so you or your doctor can get more information about trials you are interested in.

What are my rights as a patient?

The people involved in your care must treat you with consideration and respect. You have the right to:

- be told all the important details about your care
- ask questions and have them answered
- say no to any test, procedure or medication
- go to another health care provider to get more information
- know the names of anyone you talk to
- read your medical records with your health care provider
- make your own decisions about your health care
- know that your medical records will be kept confidential

What are my responsibilities as a patient?

The researchers have a right to expect certain things from you, too. As a patient, you have the responsibility to:

- be honest about your medical history and anything in your lifestyle which may affect your health
- follow instructions and take the study drug(s) as requested
- keep appointments or re-schedule them in advance
- report any changes in your health
- be sure you understand the facts before you make a complaint

What is informed consent?

Researchers are required by law to give you all the facts about a study before you join. This information must be explained in a way that you can understand. Before you join a study, you will be asked to read and sign a consent form. This is called giving ***informed consent***.

When you sign the consent form, it means that you have been given all the information about the study, and that you agree to join. The consent form is not a contract. You do not give up any rights if you sign the consent form. You can leave the study at any time.

What should I know before I sign the consent form?

Before you sign the consent form, you should know:

- the reasons for using the experimental treatment
- the risks and benefits of taking part in the study
- if there are any extra costs, doctor visits, lab tests, etc.
- what drugs you will have to take

Are there any other questions I should ask before I sign the consent form?

Before you decide to join a trial, you may want to know:

- How will information about me be handled to protect my privacy?
- Can I take the drug after the trial is over? Will I have to pay for it?
- If I get sick or develop health problems while on the trial, will I be taken off the trial?
- How can I find out the results of the trial?
- Are there other studies of this drug I should know about?
- Do I have to use birth control? If so, what kind? If I become pregnant will I have to leave the study?

What should I do If I don't understand something?

Do not sign the consent form until you understand everything in it. Keep asking questions. The staff should be able to answer most of them. However, there may not be enough information about certain drugs to answer some questions.

Why do some studies pay people to participate?

Some research studies pay people who volunteer to participate in them. Usually, studies only pay when there is no expected medical benefit to participants, such as when a new drug is being tested for only a short amount of time. Sometimes studies pay when they ask a lot of time and energy from participants, such as overnight stays in the hospital, or long surveys about personal issues.

Some researchers feel that the offer of money is not always ethical because it may tempt some people to take risks that they would not take otherwise. Ask and understand why the study is paying participants before you decide whether to join. Keep in mind that studies that pay usually do not pay until the study is over.

When studies do not pay, it is because the potential benefit of the study is felt to be enough compensation for the effort and risk of participating in it. If a study gives you free medication, check-ups, lab tests and helps you to be healthier by curing or preventing disease, then you *do* get something out of your participation.

Getting more information about specific studies

If you want to find out more about a specific clinical trial, call the person listed under "Location" for that trial. This is usually a research nurse or study coordinator. S/he will ask you some questions about your health to find out if you fit the entry criteria for the trial. It is a good idea to have a copy of your most recent laboratory tests, such as blood tests and T-cell counts, when you call.

Finding out if you're eligible: The screening visit

If the research nurse thinks you may be eligible, s/he will ask you to come in for a "screening" visit. At this visit, someone will explain the study to you, and you will give them more information about your health and your medical history. You may also have a brief physical exam and have some blood tests done.

Giving "informed consent"

If you meet all the entry criteria you will be asked to sign a consent form. When you sign the consent form it means that you have been given all the information about the study, and that you agree to participate.

The first study visit

After you have signed the consent form, you can join the study during a "baseline" visit—the first official visit of the study. A lot of information is collected during the baseline visit, so it may take longer than your regular office visit.

Followup visits

If you are taking a new drug, you will probably be asked to come back to the office for another visit in 1 - 2 weeks. This is to watch for any side effects of the drug that you may be experiencing. If everything seems to be all right, you will be asked to come back for regular followup visits. Frequency of visits may vary from daily to every few months, depending upon the study.

Keeping in touch

It is important to come to each study visit, and to let the researchers know how you are doing. It's also important to keep seeing your regular health care provider. Everyone is interested in protecting your health and safety when you are in a clinical trial, so it is important to stay in touch.

There are a number of misunderstandings about women and clinical trials. Here are the facts about some of the most common misunderstandings.

Can women with HIV join clinical trials?

Yes. Every clinical trial has requirements about who can join. If a woman meets these requirements, she can join. Most clinical trials are open to both women and men.

Women often don't get enough information about clinical trials and think that they cannot join simply because they are women.

Check the index of this Directory for studies that are open only to women, but remember that women may also join nearly all of the other studies listed.

Are there special rules about birth control and pregnancy?

Yes. In many studies, women must agree to use birth control if they have sex with men. Pregnant or nursing women usually can't join a trial of an untested drug because it is not known if the drug might harm the baby. However, there are now a few studies for pregnant women.

What happens if a woman becomes pregnant while in a trial?

A woman should know the rules about pregnancy before she joins a trial. Different trials have different rules about whether a woman can continue in the trial if she becomes pregnant.

Some women think they must have an abortion if they become pregnant while in a study. This is not true. Every woman always has the right to make her own decisions about pregnancy. No one can force you to have an abortion. However, if you choose to have the baby, it may affect your continued participation in the trial.

If you become pregnant, you may want to talk to the contact people for the studies for children listed in this guide (pages 73-88). These people are usually experts in pregnancy and women with HIV and can give you the most current information.

Services for women with HIV -- Los Angeles Area

There are too many programs and services for women in the Los Angeles area to list here. To receive a full listing, contact AIDS Project Los Angeles for a free copy of their guide to LA resources.

AIDS Project LA (213) 993-1459 (English)
(213) 993-1483 (Spanish)

Services for women with HIV -- San Diego Area

Being Alive has programs for women and children, including treatment education and advocacy.

San Diego: (619) 291-1400 or 1-800-606-2224

Services for women with HIV -- Northern California

WORLD (Women Organized to Respond to Life-Threatening Diseases). These women publish a newsletter with treatment information, and organize classes to teach themselves about HIV, including information on clinical trials. They can also offer referrals to services in the Bay Area.

You may contact WORLD at (510) 658-6930.

Check the Resources section on page 121 for more resources of interest to women.

Children and Clinical Trials

Most trials for adults do not allow children under the age of 13 to join. But there are clinical trials designed especially for children from birth to age 13 or older. Children's research is done by doctors and nurses who are experts on children's bodies and health.

Why are there trials for children only?

Children's bodies are different from adults' bodies, and HIV affects children differently than adults. For example, children get certain infections more frequently than adults, and never get some infections that adults get. It is important that your child see a doctor who knows about both HIV and children.

Because children's bodies are different from adults', a drug may work differently in children. Some drugs work very well in children and not at all in adults. A child usually needs a lower dose of a drug. Some drugs are too strong to give to children or have side effects that are worse for children than adults. Because of these differences, most researchers feel that it is better to test drugs separately in children.

Is it ethical to do research with children?

Some people think that it is never right to do research with children because children are too young to decide for themselves to take part in research. They feel it is not fair to put children at risk. Others feel that with AIDS and other life-threatening diseases that don't have a cure, the risk of the disease is greater than the risk of taking a drug that hasn't been thoroughly tested. Research may be the only chance to get certain drugs, and these drugs may be the only hope of getting better.

A child's parent or guardian must give written permission before a child can join a clinical trial. This permission is called ***"informed consent"***.

Where can I find out more about clinical trials for children with HIV?

This Guide lists trials for children at the end of the clinical trials section beginning on page 77.

You can call the contact people for the studies listed there—these people are usually medical experts on children with HIV and should be able to answer your questions.

What does "youth" mean?

People use the term "youth" differently. It can mean people from 13 to 18 years old, or 13 to 21 years old, or 13 to 26 years old. Other words used for youth are "adolescent" and "teen."

Why are youth treated differently in clinical trials?

Youth are different physically and emotionally from both children and adults. Healthcare and support programs for youth take these differences into account.

In which trials may youth participate?

Most clinical trials allow youth to join. Often people between ages 13 and 18 are eligible for both children's and adults' clinical trials. We list age restrictions for all the trials in this directory.

Do youth under 18 need permission to join a clinical trial?

Yes, minors (younger than 18 years old) need to get written permission from a parent or guardian to join a drug trial, even if they get medical care at a clinic without permission. There are people working to change the laws in this area, and they may be able to help you join a trial without your parents' permission in certain situations. See the "Common Questions" section of this Directory for an explanation of what it means to give ***"informed consent."***

Youth and Clinical Trials

Medical & Referral Services for Youth with HIV—Northern California

Bay Area Young Positives (BAY Positives)
518 Waller Street
San Francisco, CA 94117
(415) 487-1616

BAY Positives is an education, support and advocacy organization by and for young people with HIV from the entire Bay Area.

Health Initiatives for Youth (HIFY)
1242 Market Street, 3rd Floor
San Francisco, CA 94102
(415) 487-5777
HIFY provides information to HIV+ youth and their providers about clinical trials.

Larkin Street Medical Clinic
1044 Larkin Street (at Sutter Street)
(415) 673-0911
Free medical and support services for homeless and runaway youth ages 12 to 23.

UCSF Teen Clinic
400 Parnassus, 2nd Floor, Room A270
(415) 476-8626 (Dave Knopf)
Full medical and support services.

San Francisco General Hospital
1001 Potrero Avenue (between 22nd and 23rd Streets)
Teen and Adolescent Clinic (under 18 years old)
(415) 206-8376

Kaiser Teenage Clinic
2350 Geary Boulevard, 1st Floor
(415) 202-2213
Medical and support services for youth who have Kaiser insurance or MediCal.

Medical & Referral Services for Youth with HIV—Southern California

Childrens Hospital LA
Risk Reduction Program
5000 Sunset Boulevard, 4th Floor, LA, CA 90027
(213)669-2390
Free health care and treatment ot young people with HIV between the ages of 12 and 24. Case management, psychosocial and nutritionsal education services also available.

High Risk Youth Program: (213) 669-2503
4650 Sunset Boulevard #2
Los Angeles, CA 90027
Medical services for homeless youth.
Department of Adolescent Medicine: (213) 660-2450
This department has several open or about to open studies designed especially for youth. Some of these are "natural history" studies that are trying to learn about young people with HIV and their situations and needs. Call and participate!

LA County USC Medical Center: 5P21 Clinic
1300 North Mission Rd., LA, CA 90033
(213) 343-8255
Adult, maternal and pediatric care and medical services.

Youth HIV Project
5000 Sunset Boulevard, 4th Floor, LA, 90027
(213) 669-2390
Free medical crae for HIV infected youth 12 to 20 years old, support groups, case management, health education.

Children's Hospital and Health Center
3020 Children's Way
San Diego, CA 92123
(619) 576-1700

Injection Drug Users and Clinical Trials

Injection drug users and people who use illegal street drugs, such as heroin, crack and speed, have often been left out of clinical trials. There are several reasons for this.

Street drugs can cause damage to the liver or kidneys. If your liver or kidneys are already damaged, taking a study drug might cause even more harm. Some trials have complicated rules that participants must follow. Researchers may think that if you use drugs you won't show up for your clinic visits, or won't take the study drugs as directed.

Most of the clinical trials in this directory ***do not*** exclude people just because they have used illegal drugs. If you are told you cannot join a clinical trial, ask the reason why. If you are (or were) an injection drug user, one of the following reasons may explain why you cannot join the trial.

Damaged liver or kidneys

Doctors can use certain laboratory tests to find out if your liver and kidneys are healthy. This is important, because you can have harmful side effects from the study drug if your liver or kidneys are damaged. These tests are usually done during the "screening" visit. If any of the tests are "outside normal limits," you may not be able to join the trial. This is done to protect your health.

Dangerous drug interactions

It can be very dangerous to mix some drugs, or to mix drugs and alcohol. Even mixing methadone with some study drugs can be dangerous. It is important to let your doctor and the researchers know ***every*** drug you are taking, to prevent harmful side effects.

Unable to comply with the "rules" of the study

Some trials have very complicated rules, and some people find it hard to follow them. That is why, if your doctor thinks you are "unreliable," you may not be able to join a clinical trial. If you do not take the study drug as directed, or frequently miss clinic appointments, it may be impossible to learn if the drug is working, or to prevent harmful side effects.

AIDS Community Research Consortium (ACRC)
1048 El Camino Real, Suite A
Redwood City, CA 94063
(650) 364-6563

AIDS Healthcare Foundation Research Center
1300 N. Vermont Ave., Suite 502A
Los Angeles, CA 90027
(323) 913-3953

AIDS Oncology Practice at UCSF/Mt. Zion
2356 Sutter Street, 5th Floor Pavilion
San Francisco, CA 94115
(415) 567-5581

AIDS Research Alliance
621-A North San Vicente Blvd.
West Hollywood, CA 90069
(310) 358-2429

AltaMed HIV Services
5427 Whittier Blvd.
East Los Angeles, CA 90022
(323) 869-1900

Bay Area Perinatal AIDS Center (BAPAC)
1001 Potrero Avenue, Room 6D1
San Francisco, CA 94110
(415) 206-8919

Cedars-Sinai Medical Center
Division of Infectious Diseases
8700 Beverly Boulevard, #B-226
Los Angeles, CA 90048
(310) 855-3755

Center for Special Immunology
1160 Warner Avenue, Suite 415
Fountain Valley, CA 92708
(714) 753-0670

Children's Hospital Los Angeles
4650 Sunset Boulevard
Los Angeles, CA 90027
(213) 669-4537

Children's Hospital, Oakland
747 - 52nd Street
Oakland, CA 94609
(510) 428-3337

City of Hope National Medical Center
1500 E. Duarte Road
Duarte, CA 91010
(626) 301-8434

Community Consortium
3180 18th Street, #201
San Francisco, CA 94110
(415) 476-9554

East Bay AIDS Center
2850 Telegraph Avenue, Suite 110
Berkeley, CA 94705
(510) 204-1870

Eisenhower Medical Center
39000 Bob Hope Drive
Suite 206, Keiwit Building
Rancho Mirage, CA 92270

Gladstone Institute of Virology and Immunology
1001 Potrero Avenue, Building 3, Room 601
San Francisco, CA 94110
(415) 695-3820

Harbor-UCLA Medical Center
1124 W. Carson Blvd.
REI N-24
Torrance, CA 90502
(310) 222-3848

HIVCare, Saint Francis Memorial Hospital
900 Hyde Street
San Francisco, CA 94109
(415) 353-6215

Institute for HIV Research and Treatment
California Pacific Medical Center - Davies Campus
Castro and Duboce Streets
San Francisco, CA 94114
(415) 565-6660

Clinical Trials Sites

Kaiser Permanente - Los Angeles
1505 North Edgemont, 2nd Floor
Los Angeles, CA 90027
(213) 783-8172

Kaiser Permanente Clinical Trials Unit, San Francisco
4141 Geary Boulevard, Suite 219
San Francisco, CA 94115
(415) 202-3480

Kraus Medical Partners
5901 West Olympic Boulevard, Suite 310
Los Angeles, CA 90036
(213) 930-2324

LAC-USC Medical Center - Maternal Child Program
1640 Marengo Avenue
HRA Bldg., 3rd Floor
Los Angeles, CA 90033
(323) 226-5068

LAC-USC Medical Center - Norris Cancer Hospital
1441 Eastlake Ave., Room 3016 MS 34
Los Angeles, CA 90033
(323) 865-0371

Marcus Conant, MD Clinical Research
350 Parnassus Avenue, Suite 808
San Francisco, CA 94117
(415) 661-2613

Marin County Specialty Clinic
161 Mitchell Boulevard, Suite 200
San Rafael, CA 94903
(415) 499-7377

Orange Coast Medical Group
361 Hospital Road, Suite 126
Newport Beach, CA 92663
(949) 646-1111

Pacific Horizon Medical Group
2351 Clay Street, Suite 512
San Francisco, CA 94115
(415) 292-5477

Pacific Oaks Research Group
8641 Wilshire Boulevard, Suite 305
Beverly Hills, CA 90211
(310) 360-8800

Quest Clinical Research, San Francisco
2300 Sutter Street, Suite 202
San Francisco, CA 94115
(415) 353-0800

St. Luke Medical Group & Clinical Trials
1855 1st Avenue, Suite 300A
San Diego, CA 92101
(619) 235-4211

San Francisco General Hospital GI Clinic
1001 Potrero Avenue, Room 3C
San Francisco, CA 94110
(415) 206-8824

San Francisco Veterans Administration Medical Center
4150 Clement Street, Room 111 W
San Francisco, CA 94121
(415) 750-6960

Santa Clara Valley Medical Center
2400 Moorpark Avenue, Suite 316B
San Jose, CA 95128
(408) 885-4690

Sherman Oaks Hospital Research Institute
4911 Van Nuys Blvd., Suite 300
Sherman Oaks, CA 91403
(818) 205-1902

Slauson Plaza Medical Group
9436 Slauson Avenue
Pico Rivera, CA 90660
(562) 949-6069

Stanford University Medical Center
Center for AIDS Research
300 Pasteur Drive, Room S-156
Stanford, CA 94305
(650) 723-6231

UC Davis Cancer Center
4501 'X' St., G-126
Sacramento, CA 95817
(916) 734-3604

UC Irvine - Opthalmology
2000 Medical Plaza Drive, Suite 2004
Irvine, CA 92697
(949) 824-8303

UC Irvine Medical Center
101 City Drive South, Building 53
Route 81
Orange, CA 92668
(949) 456-7612

UCLA CARE Center
18033 Le Conte Avenue
BH-412 CHS
Los Angeles, CA 90095
(310) 206-6414

UCLA - Jules Stein Eye Institute
100 Stein Plaza, Room 3-110
Los Angeles, CA 90095-7000
(310) 794-5608

UCLA Medical Center - Pediatrics
10833 Le Conte Avenue
Los Angeles, CA 90095
(310) 206-6369

UCSD HIV Neurobehavioral Research Center
2760 Fifth Avenue, Suite 200
San Diego, CA 92103
(619) 543-5000

UCSD Treatment Center
150 W. Washington Street
San Diego, CA 92103
(619) 543-8080

UCSD Mother, Child and Adolescent HIV Program
2760 - 5th Avenue
San Diego, CA 92103-6325
(619) 543-8080 ext. 261

UCSF Positive Health Practice at Parnassus
400 Parnassus Avenue, 4th Floor
San Francisco, CA 94143
(415) 476-6027

UCSF Positive Health Practice at SFGH / ACTU
3180 - 18th Street, Suite 305
San Francisco, CA 94110
(415) 514-0550

UCSF Positive Health Practice at SFGH / ICTG
635 Potrero Avenue
San Francisco, CA 94110
(415) 476-9296, ext. 330

UCSF Bone Marrow Transplant Program
505 Parnassus Avenue, Room M1286
San Francisco, CA 94143
(415) 476-1241

UCSF Center for AIDS Prevention Studies
74 New Montgomery Avenue, Suite 600
San Francisco, CA 94105
(415) 597-9165

UCSF Drug Research Unit at SFGH
1001 Potrero Avenue, Building 100, Room 157
San Francisco, CA 94110
(415) 476-5906

UCSF Infectious Diseases Research
505 Parnassus Ave, Room AC30B
UCSF Box #0919
San Francisco, CA 94143
(415) 476-2308

UCSF Department of Neurology
350 Parnassus Avenue, Room 500B
San Francisco, CA 94143
(415) 502-5064

UCSF Pain Clinical Research Center
1701 Divisadero Street
San Francisco, CA 94115
(415) 885-7804

UCSF Pediatric Immunology Program
505 Parnassus Avenue, Room M679
San Francisco, CA 94143
(415) 476-9373

UCSF/SFGH Endocrinology
1001 Potrero Avenue, Building 100, Room 321
San Francisco, CA 94110
(415) 206-4090

UCSF Stomatology Clinical Center
513 Parnassus Avenue, Room S612
San Francisco, CA 94143
(415) 502-4691

University of Southern California ACTU
1300 North Mission Rd.
Los Angeles, CA 90033
(323) 343-8288

ViRx, Inc.
1375 Sutter St., Suite 407
San Francisco, CA 94109
(415) 353-5623

ViRx, Inc. - Palm Springs
1401 N. Palm Canyon Drive, Suite 202
Palm Springs, CA 92262
(760) 864-6266

Women's Interagency HIV Studies
400 Parnassus Avenue, Room AC-16
San Francisco, CA 94143
(415) 502-8056

Community Consortium Sites and Providers

The Community Consortium conducts clinical trials at over a dozen sites in the San Francisco Bay Area. Health care providers who are participating in the Consortium's clinical trials program are listed below. If you are interested in enrolling in a Consortium clinical trial and your health care provideris listed here, you can discuss enrollment during your next office visit.

San Francisco — Private Practices
Virginia Cafaro, MD
Martin Mass, MD
Kenneth Mills, MD
William Owen, MD
Carl Stein, PA

Castro-Mission Health Center — San Francisco
Nilda Alverio, MD
Jane Bailowitz, MD
Deborah Brown, MD
Toby Dyner, MD
Walter Krampf, MD
Lawrence Price, MD
Fred Strauss, MD

Kaiser Permanente HIV Trials Unit, San Francisco
Jeffrey Fessel, MD
Stephen Follansbee, MD

Mission Neighborhood Health Center — San Francisco
Colleen Foy, MD
Ricardo Alvarez, MD
Steve Leiner, NP
Richard Dolbec, MD

UCSF Positive Health Practice - UCSF (Parnassus)
Harry Hollander, MD
Amy Kindrick, MD, MPH
Katherine Kocurek, MD
John Nienow, MD
Susan Shea, NP

UCSF Positive Health Practice - SFGH (Ward 86)
Donald Abrams, MD
Gary Carr, NP
Molly Cooke, MD
Steven Deeks, MD
Rick Hecht, MD
Mark Jacobson, MD
James Kahn, MD

UCSF Positive Health Practice - SFGH (Ward 86), continued
Mary Lawrence Hicks, NP
Jill Legg, MD
Catherine Lyons, NP
J. B. Molaghan, NP
Edward Murphy, MD
Meg Newman, MD
Michelle Roland, MD
Susan Shea, NP
John Stansell, MD
Jacqueline Tulskey, MD (Ward 93)
Daniel Wlodarczyk, MD

Community Health Network Youth Clinics
Nicolette Collins, MD

Veterans Administration Hospital, San Francisco
Harry Lampiris, MD

East Bay — Private Practices
Robert Scott, MD

East Bay AIDS Center (Alta Bates Herrick Medical Center), Berkeley
Claire Borkert, MD
Steve O'Brien, MD
Susan Jacobson, MD
Jeffrey Burack, MD
Michael D'Arata, FNP

North Bay — Private Practice
Milton Estes, MD
Grace Dammann, MD
Josh Bramberg, MD
Debbie Jernberg, FNP

Access Project

1-800-734-7104
e-mail: AIDSTreatD@AOL.com
Internet:www.aidsinfonyc.org/network/access/index.html
A national clearinghouse for information about treatment access. For information about what drugs and treatments are available through federal, state or pharmaceutical-industry-sponsored programs, including:

- Medicaid and AIDS Drug Assistance Programs
- Patient Assistance /Expanded Access Programs
- Information about particular treatments.

AIDS/HIV Treatment Directory

Published twice a year by the American Foundation for AIDS Research, this directory is the most comprehensive source of information on approved and experimental treatments for HIV infections and other HIV-related disorders. Provides current information on clinical trial results, open protocols and enrollment, expanded access/ treatment IND programs, financial assistance programs, and additional resources for HIV/AIDS treatment. For subcription, contact AmFAR.
Phone: (800) 382-6327
Address: 120 Wall Street, 13th Floor
New York, NY 10002
Internet: http://txdir.amfar.org

AIDS Treatment News

Newsletter reporting on treatments for HIV / AIDS and public policy issues. Published twice a month. Subscription fee (available free or at low cost for people with limited income). Call for information. Highly respected.
Phone: (800) TREAT-1-2
(415) 255-0588
Address: P.O. Box 411256, San Francisco, CA 94141

AIDS Clinical Trials Information Service

Free national hotline, in English and Spanish, for information about AIDS Clinical Trials. Hours are Monday through Friday, 6:00am - 4:00pm (California time).
Phone: 1-800-874-2572 (1-800-TRIALS-A)

California AIDS Hotlines

(800) 367-2437
(800) 273-2437 - Niteline 5PM - 5AM PST

Gay Men's Health Crisis Treatment Issues

Reputable newsletter of experimental AIDS therapies published by Gay Men's Health Crisis in New York. Subscription charge.
GMHC Medical Information
129 West 20th Street
New York, NY 10011
Phone: (212) 807-6664
NY Hotline: (212) 807-6655
Internet: http://www.gmhc.org

Medical Alert

Newsletter of the National Association of People with AIDS
1413 K Street, NW
Washington, DC 20005

National HIV/AIDS Treatment Hotline

Treatment Information Service: (800) 448-0440
CDC National AIDS Hotline: (800) 342-2437

For federally approved treatment guidelines and information. Calls accepted from people with HIV, families, friends, health care providers. All calls are confidential.

Project Inform

Sponsors town meetings for information about and discussion of treatment twice a month. Information sheets and newsletter about available experimental drugs in treating AIDS, ARC, and HIV infection. Researches and disseminates information about where and how to obtain experimental drugs, current pricing, and what is known about dosage and clinical trials. California Hotline. Free, donations for information sheets and newsletters accepted. Knowledgeable staff.
Phone: (800) 822-7422 (national, toll-free)
(415) 558-9051 (San Francisco area)
Address: 205 - 13th St.#2001 San Francisco, CA 94103
Internet: http://www.projinf.org

Trials Search

A free computerized clinical trials matching service that provides people with HIV with personalized lists of studies for which they may qualify based on their medical history. Database covers all open trials in the United States. To receive a report, complete the Trials Search questionnaire (found in this Guide or by calling the number below), or conduct your own search at the Trials Search site on the World Wide Web. Trials Search is a service provided by the Community Consortium.

Phone: (800) 492-5777
(415) 476-5777
Fax: (415) 502-8686
Address: 3180 18th Street, #201, SF, CA 94110
Internet: http://hivinsite.ucsf.edu/tsearch

WORLD

(Women Organized to Respond to Life-Threatening Diseases)

Newsletter contains updates about clinical trials and treatment information of interest to women. Organization sponsors "HIV-University" (HIV-U) to teach women infected with HIV about all aspects of HIV disease.

Phone: (510) 658-6930
Address: 3948 Webster Street, Oakland, CA 94609

AIDS/HIV Treatment Information Resources on the World Wide Web

HIV InSite	**http://hivinsite.ucsf.edu**
AEGIS	http://www.aegis.com/
AIDS Treatment Data Network	http://www.aidsnyc.org/network/index.html
AIDS Treatment News	http://www.immunet.org/atn/
BETA	http://www.sfaf.org/beta.html
Critical Path	http://www.critpath.org/
GMHC	http://www.gmhc.org/
Harvard AIDS Institute Link Page	http://www.hsph.harvard.edu/
HIV/AIDS Treatment Information	http://www.hivatis.org
Intl. Assoc. of Physicians in AIDS Care	http://www.iapac.org/
Johns Hopkins	http://www.hopkins-aids.edu
Journal of the AMA (JAMA)	http://www.amaassn.org/special/hiv/
Medscape's AIDS Page	http://www.medscape.com/Home/Topics/AIDS/AIDS.html
Project Inform	http://www.projinf.org/
The Body	http://www.thebody.com

Northern California Treatment Education and Advocacy Resources

ACT-UP Golden Gate Chapter / Treatment Issues Committee
Political action group. Committee works to reform treatment and drug development priorities and revolutionize the health care delivery system. Many members are very HIV knowledgeable.
Phone: (415) 252-9200 Information & announcements
(415) 252-9275 Office
Address: 519 Castro Street SF, CA 94114

Asian Pacific Islander Wellness Center
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Asian-American and Pacific Islander communities. English, Cantonese, Vietnamese, Mandarin, Tagalog and Khmer spoken.
Phone: (415) 292-3400
Address: 730 Polk Street, 4th Floor, SF, CA 94109

Bay Area Perinatal AIDS Center (BAPAC)
Center at San Francisco General Hospital that studies transmission of AIDS from pregnant women to their unborn children. Good source of information about women with HIV/AIDS and pregnancy.
Phone: (415) 206-8919
Address: 1001 Potrero Ave., Room 6D4, SF, CA 94110

New Village
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to African-American gay, bisexual and transgender communities.
Phone: (415) 674-0900
Address: 1426 Fillmore Street, SF, CA 94115

Filipino Task Force on AIDS
Case management, client services, treatment advocacy, information, communication, and education on HIV/AIDS. Services targeted to the Filipino community. Tagalog/English speaking staff.
Phone: (415) 703-9880
Address: 1540 Market Street, #325, SF, CA 94102

Mission Neighborhood Health Center, La Clínica Esperanza
General medical care, clinical trials and social services for the Latino/a community. Bilingual (Spanish / English) staff.
Phone: (415) 431-3212
Address: 240 Shotwell Street, SF, CA 94110

Native American AIDS Project
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to American Indian community.
Phone: (415) 522-2460
Address: 1540 Market Street, #425, SF, CA 94102

Options Project, Positive Health Program of the UCSF Medical Service at San Francisco General Hospital
Identifies individuals with primary HIV infection and provides those individuals with clinical care. Develops effective treatment programs for HIV infections of less then seven months duration and to see if current treatment plans are capable of eradicating HIV infection when given early in the course of disease. Provides ways of referring high risk individuals into behavioral intervention programs in order to prevent infection.
Phone: (415) 502-8100
Address: SFGH Bldg. 80, Ward 84, SF, CA 94110

Proyecto ContraSIDA por Vida
Case management and treatment advocate programs help clients learn about and gain access to health care and treatment options on an individual or group basis. Services targeted to Latino communities, especially gay, lesbian, bisexual and transgender HIV positive people. Spanish and English spoken.
Phone: (415) 575-1642
Address: 2973 16th St., SF, CA 94110

San Francisco AIDS Foundation
Information and referrals to AIDS service organizations for people who need emotional or practical support. Spanish and Tagalog speaking staff. Publishes **BETA, the Bulletin of Experimental Treatments for AIDS**. **BETA** is published four times a year and has very up to date information on various aspects of HIV infection.
Phone: (415) 487-3000
Address: 995 Market Street, SF, CA 94103

Los Angeles Area Treatment Education and Advocacy Resources

AIDS Project Long Beach
2017 E. 4th St.
Long Beach, CA 90814
(562) 434-4455

AIDS Project Los Angeles
1313 N. Vine St.
Los Angeles, CA 90028
(213) 993-1459
(213) 993-1483 (Spanish)
Publishes *HIV LA*, an extensive directory of HIV resources in LA and *Positive Living*, a monthly newsletter that includes timely treatment and clinical trial updates Call for free copies or subscriptions.

AIDS Service Center
1030 South Arroyo Parkway
Pasadena, CA 91105
(818) 441-8495

Asian Pacific AIDS Intervention Team
605 W. Olympic Blvd., Suite 610
Los Angeles, CA 90015
(213) 553-1871

AIDS Prevention Team
1219 S. La Brea Ave.
Los Angeles, CA 90019
(213) 964-7820

Bienestar Latino AIDS Project
1169 N. Vermont Ave.
Los Angeles, CA 90029
(213) 660-9680

L. A. Shanti
1616 N. La Brea Ave.
Hollywood, CA 90028
(213) 962-8197

Women Alive
1566 South Burnside Avenue
Los Angeles, CA 90019
(323) 965-1564 (800) 554-4876 (Hotline)
www.women-alive.org

WomensLink
401 Hillcrest Blvd., Unit B
Inglewood, CA 90301
(310) 313-5139

Laguna Beach Resources

The Laguna Beach Community Clinic
362 Third St.
Laguna Beach, CA 92651
(714) 494-0761

Selected San Diego Area Resources

Being Alive Center for Women and Children
3265 5th Avenue
San Diego, CA 92103
(619) 298-5099
Direct services, advocacy and education

Being Alive-San Diego
4070 Centre St.
San Diego, CA 92103
(619) 294-9988
Newsletter, support groups, counseling, housing

Hemophilia Association
P.O. Box 23099
San Diego, CA 92193
(619) 560-8373

San Diego County Department of Health and Human Services / Office of AIDS Coordination
P.O. Box 85222
Administrative Center, Room 208
San Diego, CA 92186
(619) 515-6699

San Diego Health Alliance, HIV/AIDS Office
234 North Magnolia Avenue
El Cajon, CA 92020
(619) 579-8373

UCSD Medical Center
AIDS Testing and Treatment Center
2760 Fifth Avenue, Suite 30
San Diego, CA 92103
(619) 543-8080

Selected Medical Abbreviations:

- **<:** less than
- **>:** greater than
- **≤:** less than or equal to
- **≥:** greater than or equal to
- **qd:** daily
- **tid:** three times a day
- **bid:** twice a day
- **PO:** by mouth
- **PRN:** taken as needed
- **SQ:** subcutaneous (injected under the skin)
- **IV:** intravenous (injected in a vein)
- **IM:** intramuscular (injected in a muscle)
- **mg.:** milligrams
- **ml.:** milliliters
- **mm.:** millimeters

ACTG (AIDS Clinical Trials Group): a network of medical centers around the country in which federally funded clinical trials are conducted to test the safety and effectiveness of experimental treatments for HIV infection and its complications. ACTG studies are sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), a branch of the National Institutes of Health (NIH).

Adherence: the degree to which a patient follows drug schedules (compliance)

Adjuvant: any substance that enhances the immune-stimulating properties of an antigen or the pharmacologic effect of a drug

Adverse reaction ("side effect"): toxic reaction to a substance. Common adverse reactions include rash, headaches, nausea, vomiting and drowsiness; and can be as severe as anemia, seizures and liver or kidney failure.

AIDS (Acquired Immunodeficiency Syndrome): the late stage of the illness triggered by infection with human immunodeficiency virus (HIV). According to the official definition published by the CDC, a person receives an AIDS diagnosis when he or she has a CD4 (helper T-cell) countof less than 200 and/or certain opportunistic infections common with advanced immune deficiency

AIDS-Defining Illness: one of the serious illnesses that occurs in HIV-positive individuals and a reason for an AIDS diagnosis according to the CDC's definition of AIDS. Among these conditions are PCP, MAC, AIDS dementia complex, AIDS wasting syndrome, invasive cervical cancer, Kaposi's sarcoma and CMV retinitis

AIDS Dementia Complex (ADC): a degenerative neurological condition, generally attributed to HIV disease, with a wide variety of clinical presentations including loss of coordination, mood swings and loss of inhibitions, and widespread cognitive deficit.

Anabolic steroid: a synthetic steroid used to increase muscle mass and weight. Anabolic steroids are versions of the natural hormone testosterone but have fewer masculinizing effects

Anaphylactic Shock: a life-threatening allergic reaction characterized by a swelling of body tissues (including the throat) and a sudden decline in blood pressure

Anemia: the incapacity of blood to transport enough oxygen to the body's tissues. Anemia may be caused by abnormally low number of red blood cells or insufficient or defective hemoglobin, the protein that carries oxygen in red blood cells. It is a condition that is often caused by AZT as well as by other drugs and illnesses that suppress the red blood cell production in bone marrow.

Anorexia: a lack or loss of appetite that leads to significant decline in weight

Antibacterial: a substance which stops the growth of bacteria.

Antibiotic: a substance which kills or inhibits the growth of disease causing organisms, such as bacteria and fungi. For example, penicillin for some bacteria, amphotericin B or nystatin for some fungi.

Antibody: a protein produced by plasma cells in response to a specific antigen. Antibodies bind to antigens, often resulting in the inactivation of the antigen itself or the organism to which the antigen is attached. *See also* Antigen.

Antifungal: a substance which kills or inhibits the growth of a fungus.

Antigen: a substance, especially a protein, which stimulates production of antibodies.

Antiretroviral: a substance that stops or suppresses the activity of a retrovirus (for example, AZT, ddI, ddC). HIV is a retrovirus. There are now antiretroviral drugs that suppress HIV in different ways, such as protease inhibitors and reverse transcriptase inhibitors.

Glossary

Antisense Drug: antisense drugs are designed to block viral genetic instructions, marking them for destruction by cellular enzymes, in order to prevent the building of new virus or the infection of new cells

Antiviral: a substance that stops or suppresses the activity of a virus (for example, acyclovir, ganciclovir, foscarnet).

Aphthous Ulcer: a painful oral or esophageal sore of unknown cause that has a deep eroded base. Aphthous ulcers are common in people with HIV and are treated with corticosteroids or thalidomide.

Asymptomatic: infection without symptoms. Someone may have HIV disease without showing any symptoms.

AZT intolerant: someone who has severe side effects from taking AZT and cannot continue taking it.

Baseline: the initial time point in a clinical trial or treatment regimen, just before someone starts to receive the treatment in question.

bDNA assay: see Viral Load

Bioavailability: the extent to which an oral medication is absorbed in the digestive tract and reaches the blood stream.

Biopsy: removal of a small amount of tissue from the patient, either surgically or with a small needle, for microscopic examination to determine if disease is present.

Blinding: in research, refers to the process of preventing patients and/or their doctors from knowing whether the patient is taking active drug or placebo. *See also Double-blind.*

Bone marrow: soft tissue in the interior of a bone where blood cells are produced.

Bronchoscopy: examination of the bronchi (lung passages) with the aid of a bronchoscope (a tube inserted into the lungs).

Buyers' Club: a nonprofit group that imports AIDS-related therapies available in other countries but not yet approved by the FDA for use in the United States.

Candida: a white, patchy fungus which often grows in the mouth or esophagus of people with AIDS, causing pain or difficulty in swallowing. Infection with *Candida* is known as "candidiasis" or "thrush."

CD4 cell: *see* T-cell

Center for Disease Control and Prevention (CDC): the federal public health agency serving as the center for preventing, tracking controlling and investigating the epidemiology of AIDS and other diseases.

Central nervous system (CNS): the brain and spinal cord.

Cerebrospinal Fluid (CSF): fluid that bathes the brain and the spinal cord. A sample of this fluid is often removed from the body for diagnostic purposes by a lumbar puncture (spinal tap).

Cervical Dysplasia: the development of abnormal tissue on the cervix, the outlet of the uterus, may progress to cancer.Cervical dysplasia is detected through a Pap smear.

Chemotherapy: the treatment of disease by chemical agents; usually refers to cancer treatment.

CHOP Chemotheapy: chemotherapy consisting of cyclophosphamide, doxorubicin, vincristine and prednisone.

Clinical trial: a study which tests experimental medicines in human beings to see if it is safe and effective.

CMV: (abbreviation) *see* Cytomegalovirus.

Combination therapy (for AIDS): the use of two or more antiretroviral treatments in combination against HIV. *See also HAART.*

Community-Based Clinical Trial (CBCT): a clinical trial conducted primarily by primary-care physicians, rather than in academic research facilities

Compassionate use: an FDA program that makes certain experimental drugs available to seriously ill people when no other treatment exists or when the patient cannot tolerate other treatments.

Controlled Trial: a clinical study in which one group of participants receives an experimental drug while another group receives either a placebo or an approved standard therapy.

CPCRA (Community Programs for Clinical Research on AIDS): a branch of the NIH's Division of AIDS that supports clinical trials based on local networks of practicing physicians.

Cryptococcal meningitis: a fungal infection caused by *Cryptococcus neoformans* that affects the three membranes (meninges) surrounding the brain and spinal cord. Symptoms include severe headache, dizziness, nausea, loss of appetite, vision disorders and mental deterioration.

Cryptosporidiosis: an opportunistic infection of the intestines caused by a protozoan parasite (*Cryptosporidium parvum*)

Cytomegalovirus (CMV): a virus that can cause aching, fever, mild sore throat, fatigue and enlarged lymph nodes. In AIDS, severe CMV infections can produce hepatitis, pneumonia, retinitis and colitis, leading in some cases to blindness, chronic diarrhea and death.

CT Scan: a form of X-ray examination that utilizes a special beam to produce a detailed series of images of body sections. A CT scan is also referred to as a CAT scan

Data and Safety Monitoring Board (DSMB): an independent panel of clinical research experts responsible for the ongoing review and, when necessary, modification or termination of a clinical trial to insure the safety of participants.

Desensitization: gradually increasing the dose of a medicine in order to overcome severe allergic reactions.

Disseminated: spread throughout the body.

Dose-ranging or dose-escalating: describes a preliminary clinical trial in which the amount of a drug is either periodically increased or increased with each new trial arm that is added. Used to determine how well a drug is tolerated and what its optimum dose might be.

Double-blind (double-masked): trial procedure in which neither experimental subjects nor doctors know which subjects are receiving the test drug and which are receiving a placebo or other therapy. This method is believed to promote faster and more objective results, as doctors' and patients' opinions about a test drug's efficacy might otherwise bias test results.

Dysplasia: abnormal changes or growth of cells and tissues.

Efficacy: a drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed.

Encephalitis: inflammation of the brain.

Endoscopy: viewing the inside of a body cavity with a device using flexible fiber optics.

Epstein-Barr Virus (EBV): a herpes-like virus that causes one of the two kinds of mononucleosis. EBV lies dormant in the lymph glands and has been associated with Burkitt's lymphoma and oral hairy leukoplakia.

Expanded access: (also called "parallel track") a procedure established by the FDA which permits the use of investigational drugs by individual physicians. The purpose of this program is to make the drug available to patients who need it, while collecting at least some limited data on efficacy and toxicity.

Experimental drug: a drug that is being tested for use as a treatment for a specific condition in a specific population.

FDA, Food and Drug Administration: The U.S. government department that approves and regulates drugs and medical devices. Pharmaceutical companies must have FDA approval to sell a new medicine.

Fungal Infection: a range of distinct diseases caused by fungi. Candidiasis, cryptococcosis and histoplasmosis are examples of AIDS-related fungal infections.

Gene Therapy: any of a number of experimental treatments in which cell genes are altered or added to. As it concerns HIV, gene therapies attempt to provoke new immune activity or try to make cells resistant to infection.

Genotypic Testing: an experimental blood test that determines the genetic sequences of an organism. In HIV, frequently performed in order to establish whether certain mutations housing drug resistance are present.

HAART (Highly Active Antiretroviral Therapy): aggressive anti-HIV treatment usually including a combination of protease and reverse transcriptase inhibitors whose purpose is to reduce viral load to undetectable levels.

Herpes: 1) a group of viruses including herpes simplex I (HSV I), herpes simplex II (HSV II), varicella zoster (also called shingles), Epstein-Barr virus, and cytomegalovirus. 2) a common name for blisters on the mouth or genital regions caused by herpes simplex I and II.

Histoplasmosis: a fungal disease resulting from infection with *Histoplasma capsulatum*

HIV: (abbreviation) *see* Human Immunodeficiency Virus.

HIV positive: having antibodies to the human immunodeficiency virus in the body. Implies infection with HIV.

HIV RNA tests: see "Viral Load"

Hodgkin's Disease: a progressive malignant cancer of the lymphatic system.

Human Immunodeficiency Virus: a slow-acting retrovirus which many people believe to be the sole or foremost causative agent of AIDS .

Immune Thrombocytopenic Purpura (ITP): an autoimmune disease, in which the destruction of platelets (thrombocytes) leads to an increased susceptibility to bruising and bleeding.

Immunomodulator: a drug which alters, suppresses or strengthens the immune system, such as interleukins and interferons.

IND: (abbreviation) *see* Investigational New Drug.

Induction: the initiation of a particular therapy

Informed Consent: the ability of people receiving experimental therapies to make competent decisions about their medical care.

Infusion: the process of giving a substance (medication, food supplements, etc.) to a patient by injecting it into the blood stream. This procedure can either be a one-time event or continued over many hours, days or months.

Institutional Review Board (IRB): a regulating committee composed of internal staff, hospital affiliates and community members which review and approve all human trials conducted within a particular hospital or research center, ensuring that the trial is conducted in an ethical manner.

Investigational New Drug (IND): an application submitted to the Food and Drug Administration for permission to test a new drug or an old drug for a new indication in humans

ITP: *see* Immune Thrombocytopenic Purpura.

Kaposi's sarcoma (KS): an abnormal proliferation of small, poorly formed blood vessels which occurs in some people with AIDS. KS lesions may first appear anywhere on the body or in the soft palate of the mouth; they may also remain hidden in the internal organs.

Lesion: a change in tissue caused by disease. A point or localized patch of a skin disease. Other words similar to lesion include "sore" or "spot."

Leukocyte: any of the various white blood cells, which together make up the immune system.

Long-Term Nonprogressor: an individual who has been infected with HIV for at least seven to twelve years and yet retains a CD4 cell count within the normal range and no evidence of disease progression.

Long-Term Survivor: a looser term than long-term nonprogressor that indicates any person with any stage of HIV infection, including AIDS, who is stable over a period of years.

Lumbar puncture (LP): insertion of a needle into the spinal column to remove spinal fluid.. Also called a spinal tap.

Lymphadenopathy: swollen, firm and possibly tender lymph glands. Causes may range from a temporary infection (such as the flu) to lymphoma.

Lymphoma: a malignancy (cancer) of lymphocytes, the cells that are responsible for normal immune function.

MAC (also called MAI): (abbreviation) *see Mycobacterium avium-Intracellulare* Complex.

Maintenance therapy: use of a treatment to maintain a desired effect that has already been achieved.

Malabsorption syndrome: decreased intestinal absorption resulting in loss of appetite, muscle pain, weight loss and diarrhea.

Malignant: used to describe cells or tumors growing in an uncontrolled fashion, either spreading to other sites through the blood stream or invading nearby, normal tissues. By definition, cancers are always malignant, and the term "malignancy" implies a cancer.

Microsporidiosis: an intestinal infection that causes diarrhea and wasting in people with HIV. It results from two different species of microsporidia, a protozoal parasite. Possible treatments are thalidomide and albendazole.

Molluscum Contagiosum: a skin condition caused by a pox infection, distinguished by small dome-shaped bumps on the face, upper trunk or extremities.

Monoclonal antibodies: custom-made immune system pieces that are used against one specific disease-causing agent

Mycobacterium avium-Intracellulare Complex (MAC): in people with AIDS, an infection which begins in the gut or lungs and is similar to tuberculosis. Later, the infection often spreads to other organs by way of the blood stream.

Naive: patients who haven't yet started a drug (regimen) for an infection or disease.

NCI (National Cancer Institute): a branch of the NIH that oversees considerable research in HIV and AIDS-related malignancies.

Neoplasm: tissue that grows more rapidly than normal; a tumor or growth. A neoplasm that does not spread to other tissues is described as benign. A neoplasm that spreads (metastasizes) to other tissues is termed malignant, and is commonly called cancer.

Neurological disorders: disorders of the central nervous system (brain and spinal cord), such as seizures or dementia, or of the peripheral nervous system (nerves) such as a neuropathy.

Neuropathy: see Peripheral Neuropathy

NIAID (National Institute of Allergy and Infectious Diseases): the federal agency that is responsible for a great deal of the government-sponsored AIDS research. NIAID is a branch of the NIH

NIH (National Institute of Health): the federal agency responsible for overseeing government-sponsored biomedical research. It is divided into 24 institutes and research centers.

Nuceloside Analog: a type of antiviral drug, such as AZT, ddI, ddC, 3TC or d4T.

OI: (abbreviation) *see* Opportunistic infection.

Open label trial: (also called non-masked or non-randomized trial) a drug trial in which both doctors and subjects know what drug a subject is taking (and at what dose).

Opportunistic infection (OI): illness which would not normally occur in someone whose immune system is functioning properly.

Oral Hairy Leukoplakia (OHL): a whitish lesion that appears on the side of the tongue and inside cheeks. The lesion appears raised, with a "ribbed" or hairy surface and may be caused by the Epstein-Barr virus

p24 antibody test: a test that measures the amount of antibodies in the blood against the p24 antigen.

p24 antigen test: a test that detects a protein fragment (p24) from HIV's core in blood and other body fluids. Not an accurate measurement of viral activity.

Pancreatitis: inflammation of the pancreas which can result in severe abdominal pain. Pancreatitis can be a side effect of a drug, but can occur due to including gallstones, viral infection and excessive alcohol intake.

Pap Smear: a microscopic examination of the surface cells of the cervix to detect tissue changes that could be forerunners of cervical cancer.

Parenteral: not through the mouth. Intravenous, intramuscular, and intradermal routes of administration of drugs are all parenteral

PCP: (abbreviation) *see Pneumocystis carinii* Pneumonia.

PCR (Polymerase Chain Reaction) Test: a very sensitive test to measure the amount of RNA or DNA (genetic material) of a virus or other organism in the blood or tissue. PCR tests are used to test HIV viral load.

Peripheral Neuropathy (PN): nerve damage characterized by sensory loss, pain, muscle weakness and wasting of muscle in the hands or legs and feet. It may start with burning or tingling sensations or numbness in the toes and fingers. PN may arise from an HIV-related condition or be the side effect of certain drugs.

Pharmacokinetics: the study of how drugs are absorbed, processed and eliminated by the body. This helps in determining the best route of administration, dosage and dosing schedule.

Phase I clinical trials: toxicity and dose-finding clinical studies which evaluate the drug's actions in the body, its safe dosage range, how it is absorbed, distributed, metabolized and excreted from the body. These trials are usually completed within a year and involve a small number of research subjects.

Phase II clinical trials: efficacy studies which often include several hundred human volunteers. They are designed to assess the drug's effectiveness precisely and to detect major adverse reactions (side effects).

Phase III clinical trials: involve up to several thousand participants to confirm earlier findings of effectiveness and to find side effects that occur only rarely or after a long period of treatment. They may last several years.

Phase IV clinical trials: studies designed to evaluate the long-term safety and effectiveness of a drug usually carried out after licensure of the drug. Also known as "Post-Marketing" studies

Phenotypic Testing: a test that measures some aspect of an organism's functions. For example, the amount of a certain drug needed to inhibit the growth of an HIV isolate in a test tube culture. If HIV has developed resistance to a certain drug, higher than normally administered amounts of that drug will be necessary to inhibit viral activity. Resistance is characterized as high-level, intermediate or low-level.

Placebo: an inactive substance against which test drugs (active or "real" drugs) are compared. In placebo-controlled trials the control group takes a placebo, while the test group takes an experimental drug. Many such studies are double-blinded so that neither the patients nor their doctors know which substance the patients are receiving. Placebos are usually harmless.

Platelets (also called thrombocytes): blood cells which help the normal clotting of blood.

***Pneumocystis carinii* Pneumonia (PCP):** a type of pneumonia caused by a common parasite that grows rapidly in the lungs of people with AIDS. PCP is the leading cause of death in AIDS. Rarely, *Pneumocystis carinii* infections may occur elsewhere in the body.

Prodrug: a class of drug which works after being converted in the body by metabolic processes

Prophylaxis: treatment intended to prevent people from getting a disease. For example, aerosolized pentamidine and Septra® have been shown to be effective for prophylaxis against PCP.

Protease Inhibitor: an antiretroviral drug that prevents HIV from making copies of itself (replicating) by blocking an enzyme called "protease".

Protocol: detailed plan which states a clinical trial's rationale, goal, hypothesis, the drugs involved, dosage levels, methods of administration and treatment durations, as well as who may participate, their disease and its severity.

Randomized trial: in a randomized trial, participants are assigned by chance to receive one of the treatments being studied.

Rebounding: a rapid increase in the viral load of HIV positive patients

Rechallenge: to take a drug again despite previous bad side effects.

Refractory: disease that is resistant to treatment.

Regimen: any particular treatment plan specifying which drugs are used, in what dose, according to what schedule, and for how long

Remission: when the symptoms of a condition disappear. "Remission" is not the same as "cure," because a disease can sometimes come back after it has been in remission.

Renal disease: disease of the kidney.

Resistance: reduction in sensitivity to a particular drug.

Retinitis: inflammation of the retina, a part of the eye. In people with AIDS, retinitis is often caused by CMV or HSV infections. If left untreated, it leads in most cases to blindness.

Ribozyme: recombinant RNA/enzyme combination designed to fit onto and split specific viral or cancerous genetic sequences from a cell's DNA. The gene for an anti-HIV ribozyme may be inserted into a cell to protect it from the virus's activity.

Salvage therapy: treatment for patients who are non-responsive to or cannot tolerate other available treatments for a particular condition.

Shingles: see Varicella Zoster virus

Side effects: any reaction that results from a drug or therapy. The term usually refers to a negative event, such as nausea, blood disorders or neuropathy.

Spinal tap: *see* Lumbar puncture.

STD: sexually transmitted disease.

Stem cell: one of the immature cells that are the source of all blood cells. Stems cells inhabit the bone marrow where they begin their differentiation and maturation process.

Study: a general term for any of a variety of research activities involving the collection, analysis or interpretation of data.

Symptom: any condition occurring because of a disease. For example, coughing is one symptom of *Pneumocystis* pneumonia, and headaches are a symptom of cryptococcal meningitis.

Systemic: throughout the body. Sometimes applies to medications that are taken orally or parenterally that saturate the entire body

T-cells (CD4 cells): also called T4 cells or T-helper cells. The T4 cell enhances the immune response to an infection through a complex series of interactions with other types of cells.

Thrush: a *Candida* infection of the mouth and throat often found in people with HIV infection.

Toxicity: the harmful side effects of a given drug.

Toxoplasmosis ("toxo"): a disease caused by a parasite, *Toxoplasma gondii*, often involving the brain, eyes, heart, liver and lungs.

TPN (Total Parenteral Nutrition): a liquid food substitute infused directly into a vein and designed to meet a person's entire nutritional needs.

Treatment-Naive: refers to patients with no history of previous treatment for a particular condition.

Vaccine: a substance that contains all or a portion of a disease-causing organism (usually "killed" by heat or chemicals) given for prevention or treatment of a disease. By stimulating production of antibodies, the vaccine helps to protect against infection by that organism.

Varicella Zoster Virus: a herpes virus that causes chicken pox in children. Its reactivation in adults causes shingles.

Viral Load: the number of viral particles (usually HIV) measured in a sample of blood plasma. Viral load test results are given as number of HIV copies or equivalents (Eq) per milliliter. There are two tests to measure viral load: PCR and bDNA.

Virus: microscopic agent which requires a living cell in order to reproduce. When viruses infect cells they can cause disease, often killing the cells they infect. Important viruses include Human immunodeficiency virus (HIV), Herpes and Cytomegalovirus (CMV).

Wasting Syndrome: progressive, involuntary weight loss associated with advanced HIV infection.

White Blood Cells: part of the immune system that protects the body against foreign substances such as disease-producing microorganisms.

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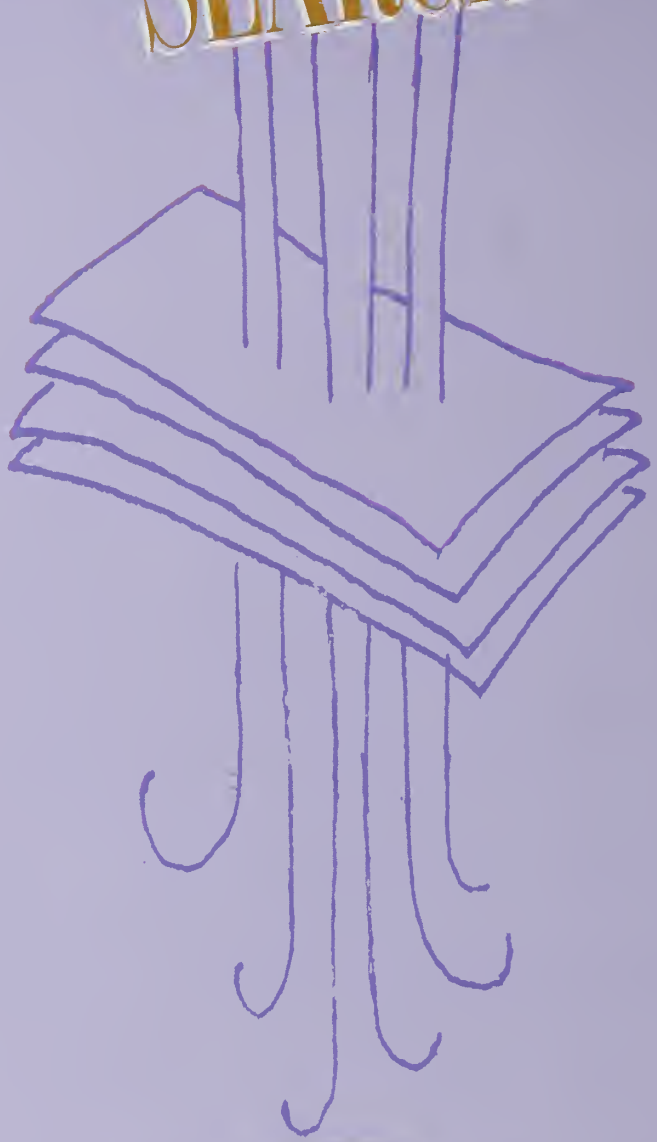

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